PSYCHOBIOLOGICAL EVALUATION OF A COGNITIVE BEHAVIORAL- AND A KINESIOLOGICAL STRESSMANAGEMENT WITH HEALTHY SUBJECTS A RANDOMIZED CONTROLLED EFFICACY STUDY

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by

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Acknowledgements

«The most exciting phrase to hear in science, is not «Eureka!» but rather «That's funny». This quotation which is attributed to Sir Isaac Asimov summarizes well my passion for science. It is not to just discover anticipated facts, but rather to stand in awe in front of a phenomenon, unknowing and simply struck by what manifests. Then start the process of understanding. I am greatly indebted to Professor Ulrike Ehlert for the chance to realize this research project at her department. It was only with her continueing support and help that this research project has become possible. Also I would like to extend my deep gratitude to Professor Reinhard Saller who inspired me in the beginning of this journey as well as supporting me in finding the financial support which enabled us to move into the direction of «Eureka!». Science, especially in less prominent areas, is only possible when organizations and individuals fund it. For the diversity as well as the progress of science it is imperative that non-monetary driven organizations contribute in research projects that might aid in the future. Therefore, I am very grateful to the Zurich based "Foundation for Complementary Medicine" that they have trusted us with their funds and laid the foundation of the project. Furthermore, I would like to thank Dr. Elvira Abbruzzese for her contagious enthusiasm and constructive insights to elevate this work to where it is today. This piece of work would not have been possible without the help of Emilou Noser, Tabea Lerch and Regula Zueger who have done a great job in the administration of the project.

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Abbreviations

AK	Applied Kinesiology
ANOVA	Analyses of variance
ANCOVA	Analysis of covariance
ACTH	Adrenocorticotropin-Releasing Hormone
BMI	Body Mass Index
CAM	Complementary and Alternative Health
CBSM	Cognitive Behavioral Stress Management
CBT	Cognitive Behavioral Therapy
CG	Control Group
CRH	Corticotropin-Releasing Hormone
GAS	General Adaptation Syndrome
HIV	Human Immunodeficiency Virus
HPA	Hypothalamic Pituitary Adrenal
IFN-γ	Interferon-γ
IK	Integrative Kinesiology
IL	Interleukin
KIG	Kinesiology Group
MMT	Manual Muscle Test
NCCIH	National Center for Complementary and Intgrative Health
NCD	Non-communicable diseases
PNI	Psycho-Neuro-Immunology
PSS	Perceived Stress Scale
RCT	Randomized Controlled Trial
SAM	Sympathetic Adrenal Medullary
SECO	State Secretariat for Economic Affairs
SIT	Stress Inoculation Training
SMG	Stress Management Group
SNS	Sympathetic Nervous System
SOC	Sense of Coherence
SRRS	Social Readjustment Rating Scale
SRS	Stress Reactivity Scale

STAI	Spielberger State Trait Anxiety Inventory
SWE	Selbstwirksamkeitserwartung (Self efficacy)
TCM	Traditional Chinese Medicine
TSST	Trier Social Stress Test
WHO	World Health Organization
YLD	Years lived with disability

Contents

Abstract

Background: Psychosocial stress has been linked to detrimental health outcomes and imposes a large economic burden. Thus, efficient and effective interventions that are able to inoculate people against stress before ailments manifest are pivotal. The purpose of the present study was twofold: First, an effectiveness study was performed to evaluate the effects of kinesiology (a mind-body intervention within complementary medicine) and cognitive-behavioral stress management (CBSM) on psychological well-being as well as the response to an acute stressor. Second, a test procedure was reviewed which might be utilized for rigorous evaluations of complementary medicine methods. Therefore, a randomized controlled study was performed to evaluate the effects of kinesiology and cognitive-behavioral stress management (CBSM).

Methods: Seventy healthy participants were randomly assigned to CBSM training, kinesiology training or a control condition. To evaluate training effects, psychometric and physiological measures were obtained. Stress reactivity of salivary free cortisol during the TSST was defined as the primary outcome measure. Secondary measures were the development of the psychometric assessments over the course of the study: depressive symptoms (ADS-K), perceived stress (PSS), stress reactivity (SRS), sense of coherence (SOC), self-concept (FKK) and self-efficacy (SWE). These psychometric components were measured before and after the training period. The control group received a training after the study was concluded.

Results: The protocol proved to be effective. However, blinded randomization was associated with substantial group differences at the outset of the study. The kinesiology group exhibited a significantly higher depression score than the other groups. While the groups did not differ in the TSST, evidence found in the post-measurement suggested improved resilience of the stress management group (SMG). The SMG exhibited desirable outcomes in depressive affect and perceived stress, improved self-concept and perceived self-efficacy as well as an im-proved sense of coherence.

Conclusion: We conclude from this study that a) the study protocol could be ameliorated by utilizing software for more elaborated allocation methods when n is small, which in turn may lead to more evenly balanced groups regarding the most important psychometric characteristics; b) it would be interesting to investigate the hypothesis that individual coping resources might be seen as a moderator affecting the strength of the relationship between the training and the responsiveness to training; and c) future studies are necessary to examine the impact of kinesiology as a method for stress management.

PART I: THEORETICAL BACKGROUND

This chapter aims to provide the framework that supports the understanding of the scientific rationale of the presented project. In order to do so a historical perspective of the concept of stress is presented, followed by up-to-date knowledge on the pathways of stress as well as the effects of psychosocial stress on physical and mental health. Then, potential stress reducing interventions are presented and a cognitive-behavioral as well as a kinesiological approach in detail introduced and discussed.

1 Evolution and development of the concept of stress

Stress is oftentimes discussed as a modern phenomenon. However, this is not the case. People have dealt with stress and its implications for as long as humans have existed. Understanding the development of the concept may elucidate the topic from a different perspective. The brief historical approach will be divided in three parts. Firstly, the stress phenomenon today will be discussed and, secondly the historical development from ancient civilizations to greek philosophers shall be outlined, thirdly then the mediaeval are focused on, to then end with the renaissance and the development of stress concepts in the 20st century.

1.1 The stress phenomenon today

Only few scientific terms have become so prominent that they are being used from kindergarten until senior homes. A New York Times columnist put it this way: „Stress is a word that is as useful as a Visa card and as satisfying as a Coke. It's non-commital and also non-commitable“ (Shweder, 1997). It's a constant factor in modern life and a frequent conversation topic. It has become an inflationary concept with vast comprehension and meaning. It can mean excitement and challenge („positive stress“), while it can also reflect an undesirable

state („bad stress“) of worry, frustration and feelings of anxiety because they threaten one's security or push one beyond the ability to successfully cope (McEwen, 2016). Therefore, „stress“ is an ambigous term and what most people are concerned about when they talk about stress is the state of being „stressed out“ (McEwen, 2005) and what it is that "stresses them out". Oftentimes it is only secondary what can be done to reduce it and only in the end of the cognitive rationale the question arises how it could be avoided altogether. The universal embracing of the concept to this day goes to prove that it refers not only to an important theoretical problem, but also touches on a real and critical aspect of life (Milczarek et al., 2009). For Chrousos et al. (1988) the term has prevailed because it attempts to address a basic principle of nature, that of maintenance of balance, equilibrium or harmony in the face of disturbing forces on the one hand and counteracting reestablishing forces on the other. It can be summarized that stress is a socio-cultural phenomenon and for once one that unites the interests of the general public as well as the scientific community in various fields.

1.1.1 Economic impact of the stress phenomenon

It also concerns governments and social policy makers (Milczarek et al., 2009) as the impact of the phenomenon stress has significant economic importance. While predominantly discussed in mental health stress itself is not a disorder, but a symptom which may be prevalent and relevant factor also in somatic diseases. Non-communicable diseases (NCD) impose a large economic burden on human health worldwide. As one of the main categories of the NCD mental health costs are the largest single cause – larger than cardiovascular disease, chronic respiratory disease, cancer or diabetes (Insel, 2008; Bloom et al., 2011). Concurrent the Global Burden of Disease Study found 2013 substantial consistency in the top disease causes: major depressive disorder and low back pain were among the ten causes of years lived with disability (YLDs) in every country (Vos et al., 2015). According to the World Health Organization (WHO, 2011) mental illnesses are also the leading causes of disability adjusted life years (DALYs), accounting for 37% of healthy years lost from NCDs. They are among the most life restricting with adverse effects to all areas of life of those affected directly, as well as those supporting them. For 2010, the global cost of mental health conditions was estimated by Bloom et al. (2011) at US$ 2.5 trillion, with the cost projected to surge to US$

6.0 trillion by 2030. This global threat and core health challenge of the 21st century (Wittchen et al., 2011) has a regional correlate. In the latest Swiss Health Observatory (Obsan) Monitoring report, Schuler and Burla (2012) have shown that 17% of the Swiss population is suffering from one or more mental illness and the number of people with symptoms that do not yet fulfill the criteria of a diagnose but already suffer is even higher. Also, psychosocial as well as work-related stress are widespread. In 2010 34% of the swiss working population felt "often to very often" stressed (Grebner et al., 2011). Compared to a previous study by the Swiss State Secretariat for Economic Affairs (SECO) ten years earlier (Ramaciotti & Perriard, 2003) this number increased 30% during this time. Meanwhile the amount of people that felt "never or sometimes" stressed diminished in the same period (Grebner et al., 2011). Stress is considered by a large body of literature to play an important role in the expression of various psychological (Clark et al., 2012) and physiological conditions. In the light of these facts the growing interest of the scientific community is almost self-explanatory and can be seen in the rising number of publications in Pubmed over the last 20 years.

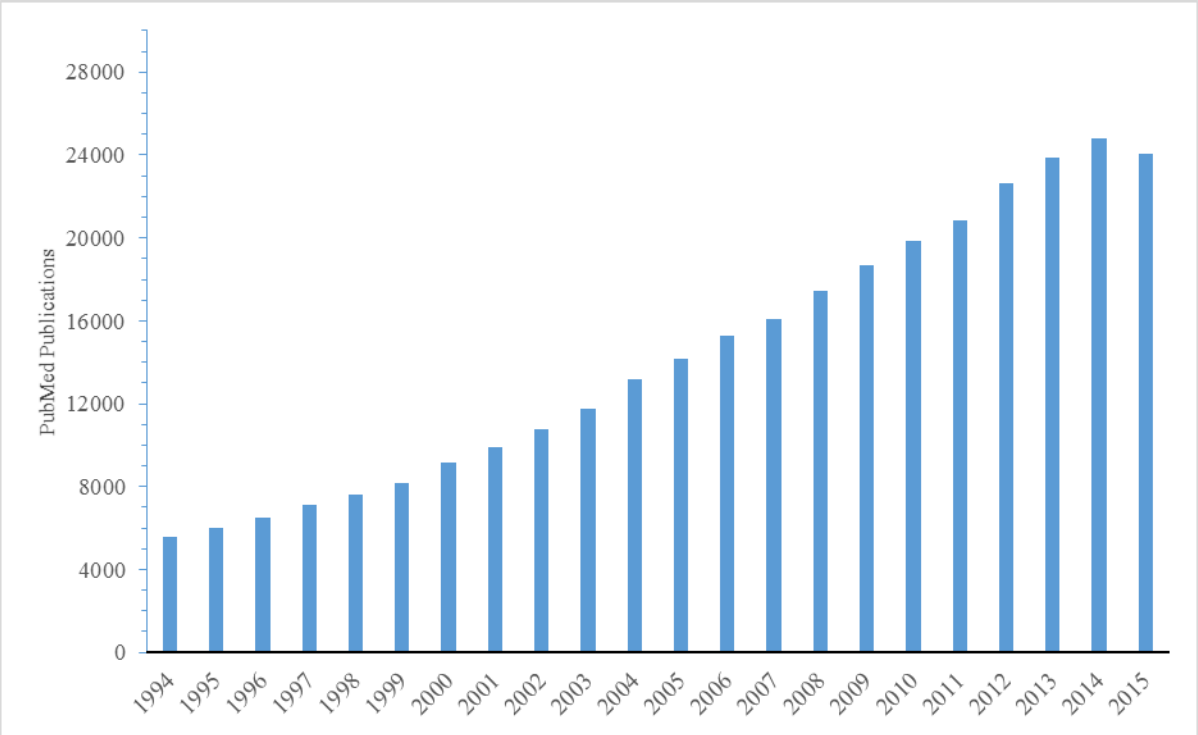

Figure 1: Development of publications with the keyword „stress" in PubMed

While described as an economic burden, stress causes suffering on the individual level as well. Solutions to this epidemic has brought to rise a whole industry with „stress management“ being part of the well-being and self-improvement industry. This a tremendous market which has been estimated to be around 8.5 billion US$ market (Banks, 2012). The business with „stress management“ brings upon everything from „eastern gurus“ to „western stressologists“ that claim their work leads to better stress-coping and well-being often without evidence of effectiveness. More so, the underlying assumptions of many stress management programs are outdated conceptualizations of stress and not contemporary knowledge about the subject. The need for solutions to cope with the challenges of daily life seems to have created a demand that does not orient itself primarily on whether a method has shown to be successful but other deciding elements.

With a demand to find solutions so high, it may be questions if there was stress before the term was coined in the 20st century? While stress is seen as something modern, it has a longer history than might be anticipated. It is plausible to argue that the stress reaction as integral part of the biological system has always been part of mankind in evolution. Interestingly, the idea of stress has already been mentioned over 500 years ago.

1.2 A historical view of the concept of stress

The history of a term shows the development of a concept over time, while the etymology of the term is concerned with the term’s origin and literal meaning. For the word “stress” its origins lie in the latin word “stringere” which means “tight, compressed, drawn together”. In Middle French “estrecier” meant “to subject (someone) to force or compulsion” and “stress” was a shortform of “destresse” (Harper, 2016). In Middle English “destresse” and “stresse” were synonymously used and meant hardship, adversity, force, pressure (McEwen & Norton, 2002). It is notable that while “stress” is seen as modern, it is deeply rooted in the history of mankind and while the conceptualizations have changed over time its inner meaning has remained.

1.2.1 From ancient civilizations to greek philosophers

In ancient civilizations medicine was characterized by religious and magical convictions. The development of diseases was attributed to the influence of supernatural powers such as gods and spirits (Fornaro et al., 2009). In accord with those beliefs healing was sought in magical properties. With the rise of the natural philosophers in the fifth century B.C. medicine underwent a disruptive period and a new paradigm developed. This new paradigm is the basis of modern medicine and also the understanding of stress. The greek philosopher Empedocles about 450 B.C. considered all matter as a mixture of essential elements existing together in a state of harmonious balance (Chrousos et al., 1988). The first reference to disturbed homeostasis and what today might be known as stressors was by Hippocrates in 400 B.C. He considered diseases as states of disequilibrium and imbalance and ascribed natural causes to diseases, therefore defining them as stressors (Chrousos et al., 1988). Disease was not seen any more as passive suffering, but as a challenge for the body to defend itself and reinstall its functions (Selye, 1976). The greek word "homeostasis" means " steady state and meant the steady, harmonious state of mind and body. Hippocrates was the first to talk about the adaptive responses of the body and introduced the concept of the healing forces of nature, later called by the Romans "vis medicatrix naturae" (Chrousos et al., 1988). The doctors task was seen to support the innate self-healing process with different treatment methods.

Table 1: The chronology of stress as a concept

Empedocles 500 - 430 B.C.	Matter consists of essential elements and qualities in opposition or alliance to one another
Hippocrates 460 - 375 B.C.	A harmonious balance of the elements and qualities of life is health – disharmony is disease.
Sydenham 1624 - 1689	Symptoms and signs of a disease arise also from the reaction of the patient's system.
Robert Hook 1635 – 1703	Hooke's law: Law of elasticity which is concerned with how physical structures withstand heavy loads. The term stress surfaced in physics.
George Beard 1839 – 1883	Connection between nervous disorders and everyday life. Definition of neurasthenia as medical condition with exhaustion of the central nervous system's energy, which was attributed to social life and civilization.

Claude Bernard 1813 – 1878	Originated the term "milieu intérieur": the principle of a dynamic internal physiological equilibrium.
Walter Cannon 1871 – 1945	Termed the "fight or flight reaction", as well as coined the concept of "homeostasis".
Hans Selye 1907 – 1982	"The general adaptation syndrome": the non-specific response of an organism to stressors.
John Mason 1924 – 2014	The HPA axis response is not a unvarying reflex, but one that may be influenced by stressor characteristics (uncontrollability and unpredictability). Recognized the bidirectionality of the stress response and the importance of individual variability in it.
Richard Lazarus 1922 - 2002	The stress response must be influenced by emotions and personal meaning because the same stressor did not reliably evoke a stress response in different individuals.

1.2.2 Mediaeval times – or birth of the term stress

With the fall of the roman Empire there was significant change in the practice and teaching of medicine. The development of "monch medicine" in the fifth and sixth century D.C. which was a combination of germanic folk medicine and fragments of medicine from ancient times (Porter, 1999). According to Gelo et al. (2014) the important concept during this time was iatrotheological, this meaning that sickness was often considered a punishment from higher powers for a violation of rules of commandments. Even if natural causes were present the disease was attributed to a divine plan. In the eleventh century medicine shifted to universities because clericals were prohibited to practice medicine (Porter, 1999). While this time period is not the period of great importance to the development of medicine, it is relevant because the term stress emerges for the first time. In a fourteenth century poem by Robert zu Brunne the word "stress" may be mentioned for the first time:

"That floure ys kalled 'aungelys mete`
That God gave the folk to ete
When they were yn wyldernes
Forty wyntyr, yu hard stres"

This was the poets interpretation of the heavenly manna sent to the Israelites as they wandered in the desert (McEwen & Norton, 2002). It is obvious that the word “stres” in this context had no positive meaning and it may be interpreted that the meaning was more in the direction of burden or hardship. While usage of the term in this time might have been different then today it is still astonishing that it has been used in a way that it is similar to today’s usage. Burden, strain and social as well as economic hardship are external factors that make life more challenging and today at least the lay population uses the term mostly in this direction.

1.2.3 From Renaissance to the 20th century

While the development in medicine in the Renaissance brought upon various discoveries such as the contributions in anatomy of Andreas Vesalius, or the works in cardiovascular research of William Harvey especially one is relevant for the development of the concept of stress (Heinrichs, 2006; Toledo-Pereyra, 2015). In the years of the Renaissance Thomas Sydenham extended the Hippocratic concept of disease as a systematic disharmony brought about by disturbing forces, when he suggested that an individual’s adaptive response to such forces could itself be capable of producing pathological changes (Chrousos & Gold, 1992). An idea that would later become relevant for the science of stress. The renaissance did develop the science of medicine but it stayed bound to the principles of the classical era.

It was with the emergence of the “new science” with a mechanistic worldview and the experimental approaches that a disruptive step was established. This was the basis for the development of modern medicine (Heinrichs, 2006). The idea that the human body resembles a machine has its roots in the idea of Aristoteles. But this mechanistic view revived in the seventeenth century with its most prominent proponent René Descartes (1596-1650). The conviction of the mechanistic worldview was that the mechanisms and laws of the non-living world also apply to humans (Porter, 1999). In this era the term stress emerged from everyday language and became a scientific terminus by the works of Robert Hook. The physicist and biologist Hooke was concerned with how man-made structures (e.g. bridges) could be made

to withstand heavy loads and resist buffeting by winds, earthquakes, and other natural forces that threaten their stability (Cooper & Dewe, 2004; Lazarus, 1993). For Hook *load* referred to a weight on a structure, *stress* was the area over which the load impinged, and *strain* was the deformation of the structure created by the interplay of both load and stress (Lazarus, 1993). This has become known as the *Law of elasticity*. Despite the difficulties involved in the transition from physics to other disciplines, the similarities of these terms with contemporary terms are astounding. Hook's analysis influenced early 20th century models of stress in physiology, psychology, and sociology tremendously. The theme that survived into modern times is that stress is an external demand placed on a bio-psycho-social system (Lazarus, 1993). The conviction of the body as machine-like, proved to be fertile ground for two other ideas. Firstly, if the body were like a machine and machines are subject to wear and tear, then the same might hold true for the body. If machines deteriorated it was assumed that the same might be true for humans. The discourse then shifted towards the impact on the body of the wear and tear of life (Doublet, 2000). Secondly, the analogy led to the idea that like a machine the body would need energy to help it function. Depending on the amount of this energy, the body will, like a machine, perform well, poorly, or even stop (Cooper & Dewe, 2004). Just as every machine needs energy to properly function, it was assumed that this had to be true for humans to. For humans it was assumed that the nerve cells would produce this energy (Doublet, 2000). The quickening pace of life and the impact this was having on health and well-being led to the fear that the human nervous system was ill-adapted to cope with the increased complexity of modern life (Cooper & Dewe, 2004). Doublet (2000) reports that writers of the time concluded that "at least a third of all diseases were of nervous origin". The noted American physician George Beard suggested that pressing demands of nineteenth-century life may lead to a circuit overload of the nervous system and he described this state as "neurasthenia" – a weakness of the nervous system leading nervous exhaustion. Cooper and Dewe (2004) see Beard's work as important because he helped to remove the social disapproval attached to ailments like anxiety, unaccountable fatigue and irrational fears but even more importantly he attempted to focus on the role played by society in the production of mental illness. During the same time period Claude Bernard (1813-1878) extended the notion of harmony or the steady state, initially posited by Thomas Sydenham during the Renaissance, by introducing the concept of "milieu intérieur", or the principle of a dynamic internal

physiological equilibrium (Chrousos & Gold, 1992). Bernard's idea was that the internal environment of living organisms must remain fairly constant in response to changes in the external environment (Selye, 1973). Therefore, the internal medium of the living organism could not be merely a vehicle for carrying nourishment to the cell, but rather "it is the fixity of the *milieu intérieur* which is the condition of free and independent life" *("La fixité du milieu intéreiur est la condition de la vie libre, independante.")* Bernard described the physiological capacity of the extra-cellular fluid environment to compensate for external variations with the purpose of maintaining and equilibrating the internal environment and hence maintaining the vital condition (Gross, 1998). According to Bernard survival is determined by consistent maintenance of the internal environment via "continual compensatory reactions" (Doublet, 2000). The idea of "milieu intérieur" therefore refers also to the idea that nothing within the body must be allowed to deviate too far from its normal equilibrium; if something does, then the individual will become ill or may even die (Selye, 1973). The importance of Bernard's work is best summarized by McEwen and Norton (2002): "He introduced the thinking that eventually led to the concept, and science, of stress."

1.2.4 Development of stress concepts in the 20st century

On the basis of Bernard's work, Walter Bradford Cannon (1871-1945) coined the term "homeostasis" (from the Greek homoios, or similar, and stasis, or position) and popularized it in his book *Wisdom of the Body* (Cannon, 1932). The author described in greater detail how the internal environment is regulated by an organism to equilibrate internal and external demands, maintaining stable conditions. Moreover, Cannon suggested that any threats to homeostasis cause a sympathoadrenal activation (Goldstein & Kopin, 2007). Already in 1914 he had described the "emergency reaction", involving the activation of the sympathetic nervous system, in his concept of "fight-or-flight". Whenever an organism perceives a threatening stimulus, a pattern of physiological changes helps the organism to adapt quickly to the situation. The preparation of the organism for fighting or fleeing involves, among other things, a rise in catecholamines, an increase in heart rate, breathing frequency and blood pressure as well as dilatation of the pupils, reduced secretion of saliva and vasoconstriction

(Abbruzzese, 2011). This concept of an emergency reaction was extended by Hans Selye (1907-1982). Selye's contribution to the field of stress is one of great importance as his research had an extraordinary impact on biology and medicine (Mason, 1975). Newton (1995) described Selye as a "celebrant of stress" and possibly no person in recent times has influenced stress theory and research more than he has (Lazarus, 1977). However, it is noticeable that in Selye's prewar mainstream articles not one of them made any reference to "stress" (Newton, 1995). Later he introduced the concept of stress to describe the reaction of an organism to a threat of the inner equilibrium. Selye assumed that stress is a complex, but nonspecific pattern (Ehlert, 2003).

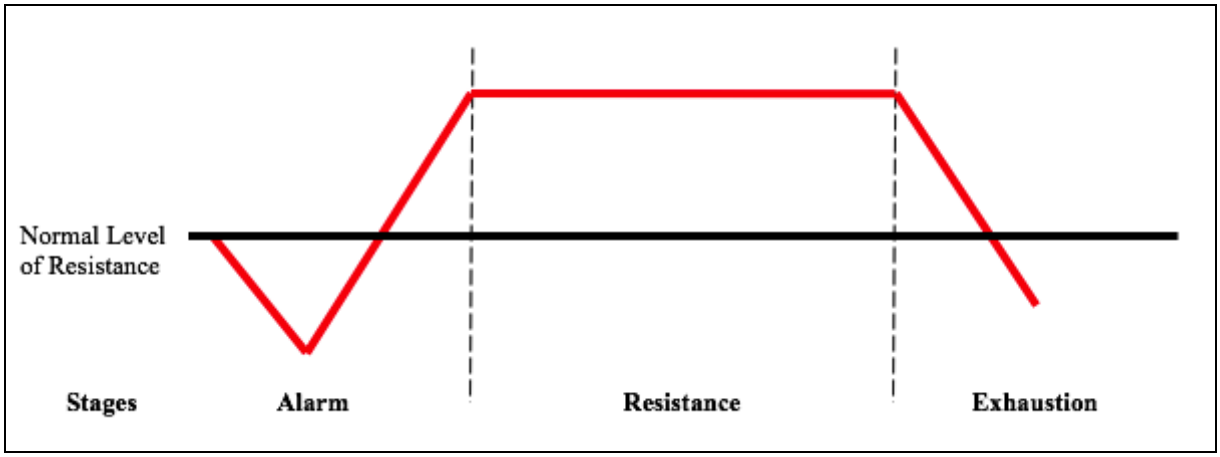

Figure 2: The three phases of General Adaptation Syndrome (Selye, 1973)

Selye proposed the "General Adaptation Syndrome" consisting of three universal stages of coping with a stressor – an *alarm*, a *resistance* and an *exhaustion* phase (Selye, 1936). In the initial *alarm* phase, which is analogous to Cannon's "fight or flight" response, the body is prepared to deal with threatening situations. The homeostasis is disturbed, and therefore the sympathetic nervous system and as a consequence the adrenal medulla, are activated and the emergency activation is induced. Along with the sympathoadrenergic system, another, slower system is triggered: the hypothalamic-pituitary-adrenal axis. This activation leads to a steep increase of glucocorticoid levels and as a consequence of this process, immunosuppressive effects can be observed (Goldstein & Kopin, 2007; Selye, 1950). In the *resistance* phase complex adaptive reactions are intensified to restore the inner equilibrium. However, if the stress situation endures, the parasympathic nervous system is activated as a counter-steering

process, diminishing the dominance of the sympathic nervous system. However, catecholamine and GC levels remain high. In the *exhaustion* phase, the adaptive capacity is exhausted and the body encounters serious problems in allocating energy, resulting in adaptation problems (Selye, 1950; Ehlert, 2003). For Selye it was clear that not all states of stress were noxious and he distinguished this by coining the terms "eustress" and "distress". He believed that mild, brief, and controllable states of challenged homeostasis could be perceived as positive to emotional and intellectual growth. Contrary to this was "physical and emotional distress" which was more severe, uncontrollable and protracted that he believed led to disease states (Chrousos & Gold, 1992).

Later a different approach was taken in in the early 1950s, an era where psychology focused on understanding human behavior by first understanding simple organisms engaging in simple behaviors learned by rewards or punishment (Fink, 2009). Mason (1968, 1975) was able to document substantial variation in elements of the GAS response as a function of the individual, its history as well as the situation. This led to questions regarding the specifity of the "nonspecific" GAS response (Ganzel et al., 2010). Furthermore, he discovered that whenever ist was possible to substantially reduce or remove the noxious "psychological collateral variables" of the stressor the GAS response failed to appear. In 1975 Mason concluded:

> *"The knowledge that the psyche is superimposed upon the humoral machinery for endocrine regulation drastically complicates our whole view."*
> (Mason, 1975)

Similarily, Richard S. Lazarus and colleagues were surprised to find that one and the same stressful event did not reliably evoke a stress response. It was reasoned that the stress response must be influenced by emotions and by personal meaning of the potentially stressful situation (Lazarus et al., 1952). Consequently, he posited a new stress paradigm which became to be known as the transactional theory of stress and integrated cognitions as mediating process. This model has then been further developed and extended.

The history of the term stress began in medieval times as part of vernacular language, then it was “borrowed” by physics where it was used to describe how physical materials react to external force and was later taken aback into social sciences and everyday language.

2 Principles of stress: models, physiology and measurement

What Hermann Ebbinghaus stated for psychology as such is, slightly amended, true for stress as well: Stress has a long past, but only a short history. As stress is a psychobiological pattern to react to life and the perception of it, the science and theoretical conceptualization of the subject is relatively new. At the initial stage of a new research field science may be (mostly) observational, but this phase should, according to Popper (1959), then give way to a more theory- and model-based stage that provide insights and direction to guide future developments. Therefore, the most discussed models of stress, the physiological basis as well as the possibilities to measure stress are indispensable in order to depict the theoretical field of stress comprehensively. This is the focus of the first chapter following.

Thereafter, it will be shown that the stress reaction has a biological foundation that seems to have been an evolutionary advantage. The popular perception of stress is mostly encompassed by symptoms such as agitation, irritability, anxiety, feelings of hopelessness or fatigue. However, there is a root that leads to this perception that may be summarized as “feeling stressed out”. This cause is referred to in the academic framework as stressor. While in the popular framework of stress the stressor per se is seen as the cause to being “stressed out”, the academic field focuses on what happens within the mind/body system that leads to a stress response and consequently behavior. Therefore, it will be shown that stress has two components: a situation or event that may be perceived as burdensome and then the reaction to it. How the individual deals with the challenge then is referred to as stress management or coping (Ehlert et al., 2013; Lazarus, 1993). In order to depict a clear picture the models of stress will be outlined and following the physiological basis as well as the measurement.

2.1 Models of stress

The stress models that have guided research and thinking have mostly been developed in the 19th and 20st century. The theories differ substantially in their view of the topic. While one

cluster of theories perceives stress as the source of burden, for another cluster it is primarily a specific reaction to it and for the third cluster it is about the association between the stimulus and its reaction to it. In short: **Stress** has been viewed as a *response*, a *stimulus*, and a *transaction*.

2.1.1 Stress as a *response* (Cannon, Selye)

Walter Cannon (1932) may have been the first modern researcher to frame stress as a response model. Cannon was principally concerned with the effects of cold, lack of oxygen, and other environmental stressors on organisms. He reasoned that even though low level stressors could be withstood, prolonged or severe stressors may lead to a breakdown of biological systems (Hobfoll, 1989). Selye (1976) continued with the theoretical frame of stress as a response. He depicted stress as an orchestrated defense operated by physiological systems designed to protect the body from environmental challenge to bodily processes (Hobfoll, 1989). Selye described stress as a physiological response and therefore a dependent variable with three concepts:

- Stress is a defensive mechanism
- Stress follows three stages: alarm, resistance, and exhaustion.
- If stress is prolonged or severe, it may result in diseases of adaptation

Selye postulated the General Adaptation Syndrom (GAS) which describes three stages: The alerting response, resistance, and exhaustion. He felt that there was a common reaction to outside stressors following the sequence of the three stages (Hobfoll, 1989). Selye's assumption of uniformity of response has been challenged by Lazarus and Folkman (1984) or Mason (1968, 1975). In the response-centered models research emphasis is mainly on the reaction patterns and the stimulus constellation is of minor interest.

2.1.2 Stress as a *stimulus* (Caplan, Holmes & Rahe, Lindemann)

The stimulus-oriented models of stress are diametric to the response models. The focus here lies on what causes stress, the nature of it – the stressors. The theory of stress as a stimulus was introduced in the 1960s, and viewed stress as a significant life event or change that demands response, adjustment, or adaptation (Stangor & Walinga, 2010). Holmes and Rahe (1967) created the Social Readjustment Rating Scale (SRRS) consisting of forty-two life events scored according to the estimated degree of adjustment they would each demand of the person experiencing them (e.g. death of a loved one, marriage / divorce, change or loss of job). The problem with this theoretical approach is that it assumes the following:

- Change is inherently stressful
- Life events demand the same levels of adjustment across the population
- There is a common threshold of adjustment beyond which illness will result

Therefore, events are considered stressful on the basis of whether they normatively lead to stress. If a stimulus mostly leads to emotional upset, psychological distress, or physical impairment or deterioration, the stimulus is said to be a stressor (Hobfoll, 1989). The individual person was therefore viewed as a passive recipient to stress and the model ignored important variables of the individual (e.g., life experience, prior learning, support networks, personality). While the theory as such has its limitations, Hobfoll (1989) singles out that by creating a taxonomy of stressful event an anchor point by which the differences in how people react can be compared and through which the nature of the events can then be further categorized. Outlining events that are likely to lead to stress responses limits the world of events that would need to be studied and may give the opportunity to focus research on areas that concern a significant amount of people.

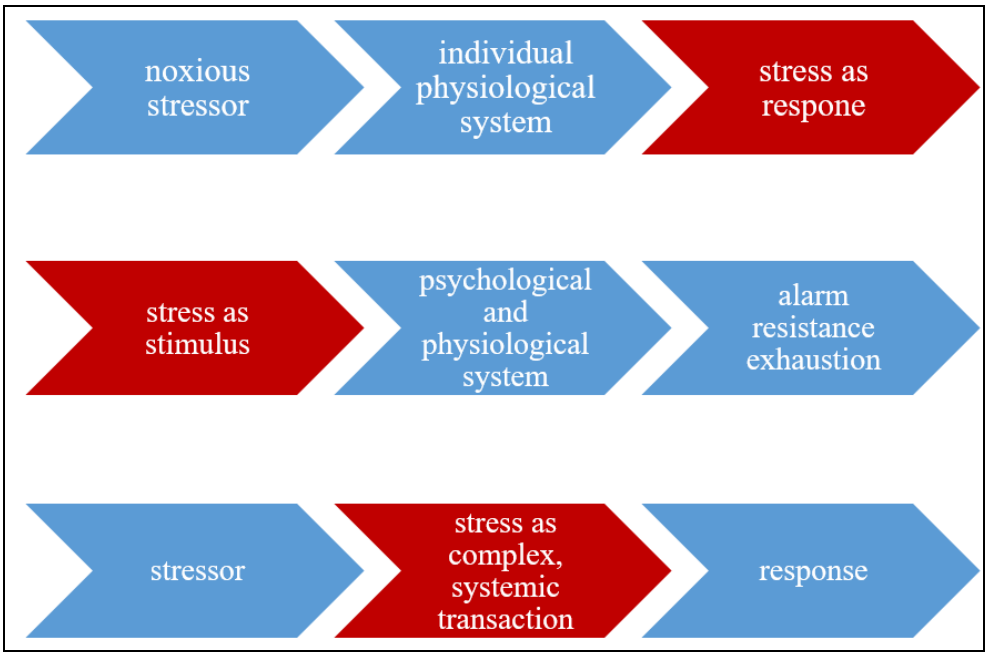

Figure 3: Theories of stress as response, stimulus, and transaction (Stangor & Walinga, 2010)

2.1.3 Stress as a transaction (Lazarus, Lazarus and Folkman)

An important perspective that is influential to stress researchers to the present time and maybe the most commonly adopted is the transactional theory of stress and coping (Lazarus, 1966; Lazarus & Folkman, 1984). Lazarus (1966) was convinced that the perception of stress was significantly dependent on the individual's evaluation of a situation. He published an elegant integration of previous research on stress, health, and coping that placed a person's appraisal of a stressor as well as the perception of one's own resources at the center of the stress experience. For Lazarus and Folkman (1984) stress is not the product of imbalance between demands and response capacity but the individual's perception of these factors. According to how the individual appraises a stressor determines the coping reaction with or to the stressor. Therefore, if a stressor is experienced as discomforting this is influenced by a variety of personal and contextual factors including capacities, skills and abilities, constraints, resources, and norms (McVicar et al., 2013). The model has been modified and extended over the years Lazarus and Folkman (1984) unpacked the concept of interpretation further in their model of stress appraisal. This is based on two successful processes: primary appraisal and secondary

appraisal. Primary appraisal involves assessing the relevance of a situation and if relevant to the individual it may be appraised as benign or stressful. When a situation is regarded as stressful, the stress can be considered as a challenge, threat or harm/loss (Lazarus, 1993). Secondary appraisal involves assessing what coping possibilities the individual possesses or believes to possess. For Lazarus and Folkman (1984) coping implied to constantly change efforts, cognitive and behavioral, to manage specific external and/or internal demands that are appraised as strenuous or exceeding the resources of the individual. The model was further developed to distinguish between emotion-focused and problem-focused coping. Additionally, the reappraisal process was introduced which is ongoing and involves continually reappraising both the nature of the stressor as well as the resources available for responding to it.

2.1.4 Homeostasis plus: The concept of allostasis (Sterling & Eyer, McEwen)

The principle of homeostasis is fundamental and a basic principle to all stress concepts mentioned. The term coined by Cannon (1932) describes how the internal environment is regulated by an organism to equilibrate internal and external demands and therefore ensuring stable conditions. While homeostasis suggests narrow ranges of activity for internal biological parameters, this is true for physiological parameters such as blood oxygen or pH but not for many others (McEwen, 1998). The homeostasis concept has been modified by Sterling and Eyer (1988) and was later extended by McEwen (1998, 2005, 2016) to a framework that enhanced the neurobiological understanding of stress. While the original conception of homeostasis grounded in a) the assumption that there is an optimum state to any given measure in the body and b) that the ideal set point is reached by a local regulatory mechanism. The concept of allostasis augmented this view. Regarding the first point it seems evident that what is ideal under basal conditions may be different than what is “ideal” during stress and regarding the second point it seems apparent that set points may be regulated not only by one mechanism but by a myriad (McVicar et al., 2013; Sapolsky, 2004). Systems such as the HPA axis, the autonomic nervous system, the metabolic systems and the immune system respond to the body state as well as the external environment and are concerned with achieving “stability through change” – this is called allostasis and was first termed by Sterling and Eyer (1988)

when they explored how the cardiovascular system adjusts to resting and active states. It is the process of the aforementioned systems to protect and adapt the individual to adversity and threats (real or implied) that is referred to as allostasis and is an essential component of maintaining homeostasis. The idea was then applied to other physiological mediators, such as the secretion of cortisol as well as catecholamines (McEwen, 1998). However, allostasis is not simply about the brain coordinating physiological reactions but one that is closely coupled to the psychological makeup of the individual and therefore may include changes in behavior as well. Another difference to homeostasis is that the setpoints of the systems may change over time. This adaptation may cause problems and is then termed as allostatic (over)load. The concept was proposed to refer to the wear and tear on the body and brain resulting from chronic overactivity or inactivity of physiological systems that are normally involved in adaptation to environmental challenge. It is the repeated cycles of allostasis as well as the inefficient turning-on or shutting off of these responses that may result in allostatic load. Hence, McEwen and colleagues distinguish between short-term adaptive actions (allostasis), which can be protective, and long-term effects (allostatic load), which can induce damage to an individual (McEwen et al., 2015a). The concept of allostasis and allostatic load is proposed as a concept of a cascade of cause and effect that begins with primary stress mediators (cortisol and catecholamines) and leads to primary effects and then to secondary (the summarized outcome of the primary effects, i.e. sustained elevation of glucose as a result of elevated cortisol levels) and tertiary outcomes in the form of diseases and disturbances.

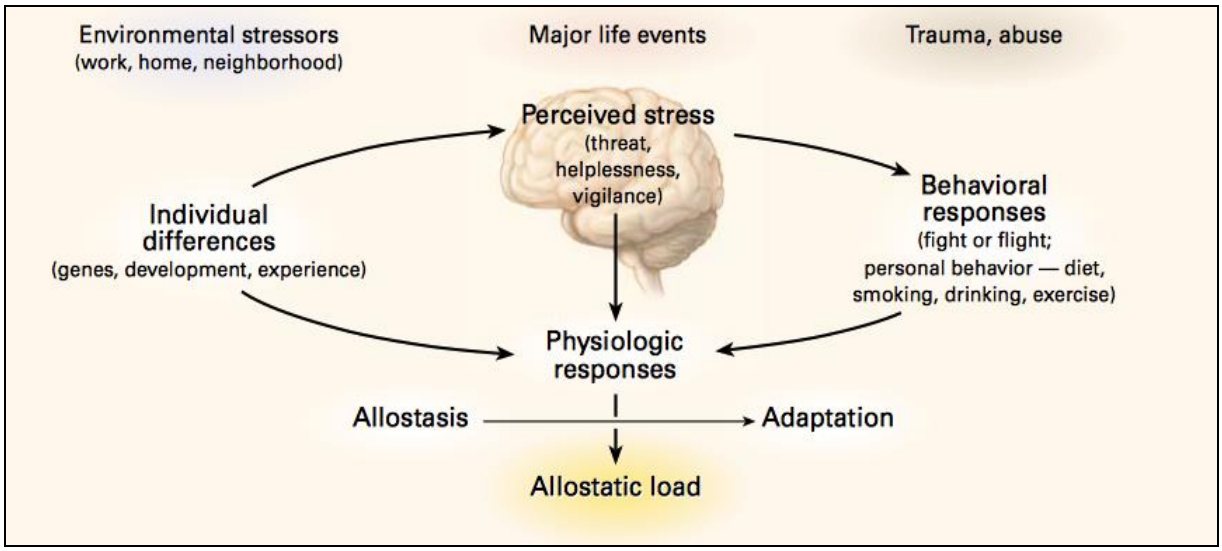

Figure 4: The model of allostatic load (McEwen, 1998)

The model offers the possibility to integrate psychological, behavioral, genetic as well as (molecular) biological factors to explain short- and long-term effects of "stress". It consists of four key features: 1) The brain is the integrative center for the coordination of behavioral and neuroendocrine responses to challenges, 2) there are individual differences in coping with challenges based on individual genetic, developmental and experiential differences, 3) Within the individual lies the capacity to adapt (turning on and shutting off physiological responses efficiently) and 4) Allostasis has a price that is related to how inefficient the response is, or how many challenges an individual experiences. Various factors contribute to allostatic load such as genetic predisposition, early development as well as learned behaviors reflecting life style choices (i.e. exercise, diet, drinking and smoking) (Seeman et al., 1997; McEwen, 2016). Allostatic load may be subdivided into four subtypes:

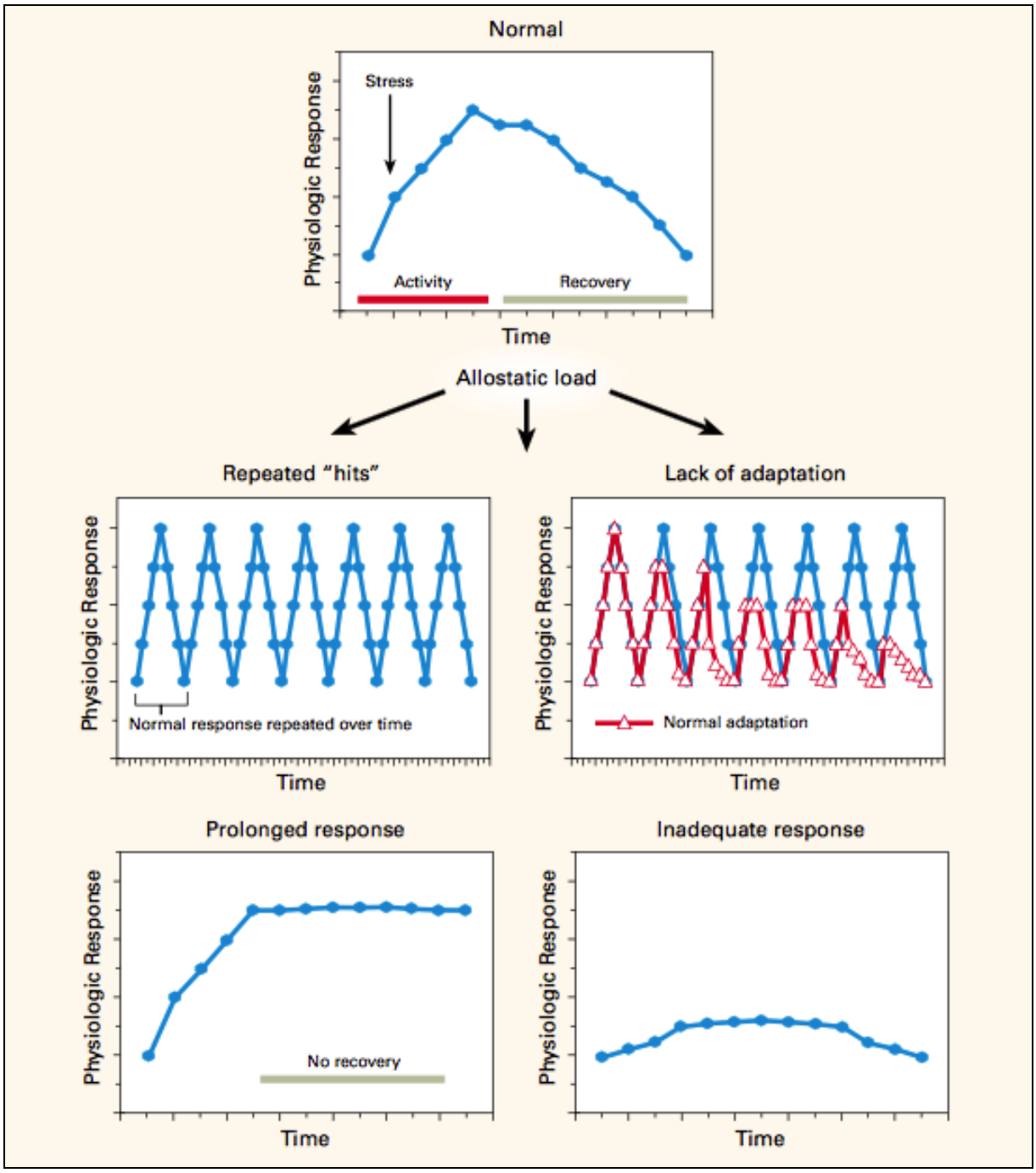

Figure 5: The four types of allostatic load (McEwen, 1998)

The first type of allostatic load is simply "too much stress" in the form of repeated events that lead to repeated elevations of stress mediators over long periods of time. The second type involves a failure of adaptation to an identical stressor, while the third type is a failure of shutting off either the hormonal stress response or to display the normal trough of the diurnal

cortisol pattern. The last type of allostatic load involves an inadequate hormonal stress response which allows other systems to become overactive (i.e. the inflammatory cytokines) (McEwen, 1998).

As adaptation to potentially stressful challenges involve activation of neural, neuroendocrine and neuroendocrine-immune mechanisms the focus shall now be on the physiology of the stress system with a focus on the hypothalamic-pituitary-adrenal axis (HPA axis) even though the sympatho-adrenal medullary (SAM) system also has its role in the process.

2.2 Physiology of the stress reaction

The central organ of stress as well as adaptation to social and physical stressors is the brain. It determines what is threatening, stores memories, and regulates the physiological and behavioral responses to stressors (McEwen et al., 2015a). However, stress involves both the brain and body as well as their interaction. In the evolution mammalian organisms, including human beings, have developed a complex and highly efficient and flexible system whose main function it is to maintain homeostasis in both the resting as challenging states (Chrousos & Gold, 2006; McVicar, 2013). It is a complex interaction of the central nervous system (CNS), the autonomic nervous system (ANS) as well as the endocrine system. Therefore, the central stress system sits in a pivotal location on the base of the brain. According to Stratakis and Chrousos (2006) the key central coordinators of the stress system are the parvocellular corticotropin-releasing hormone (CRH, also termed corticotrophin-releasing factor CRF) and arginine-vasopressin (AVP) neurons in the paraventricular nuclei (PVN) of the hypothalamus, along with the CRH neurons of the paragigantocellular and other nuclei of the medulla, and the catecholaminergic neurons of the locus coeruleus (LC) and other cell groups of the medulla and the pons. Constantly being challenged by intrinsic and extrinsic forces to maintain a dynamic equilibrium the stress system receives input from multiple sources, integrating them, and itself providing input to multiple sites of both the CNS and the periphery. Inputs arise from the sensory organs, viscera, blood vessels, musculature, and other sites through the cranial and peripheral nerves, sensory afferent fibers, and afferent autonomic

nerves as well as via the blood stream. Additionally they come from the brain cortex, via the associative cortex, the amygdala, and the hippocampus, and from the mesocorticolimbic or reward system (Chrousos & Gold, 2006; McEwen, 2012). Output of the stress system goes not only to the key players in the physiological stress response, the HPA axis and the SAM system, but also other target sites such as the arcuate nucleus of the hypothalamus and the spinal cord, the brain cortex, the amygdala and hippocampus, and from the emotional brain through the mesocorticolimbic system (Ehlert et al., 2013; Koolhaas et al., 2011). Chrousos and Gold (2006) summarize this simplistically in the following manner:

> *The stress system receives information from the environment and the body through the various sensory systems and the bloodstream, from the thinking brain through the amygdala and hippocampus, and from the emotional brain through the mesocorticolimbic system.* (Chrousos & Gold, 2006)

Under conditions of stress mostly both peripheral limbs of the stress system, the HPA axis and the SAM system, are being activated. While the SAM system reacts via neuronal activation within seconds to a threat, the HPA axis is activated within minutes in a second wave (McEwen et al., 2015a; Sapolsky et al., 2000).

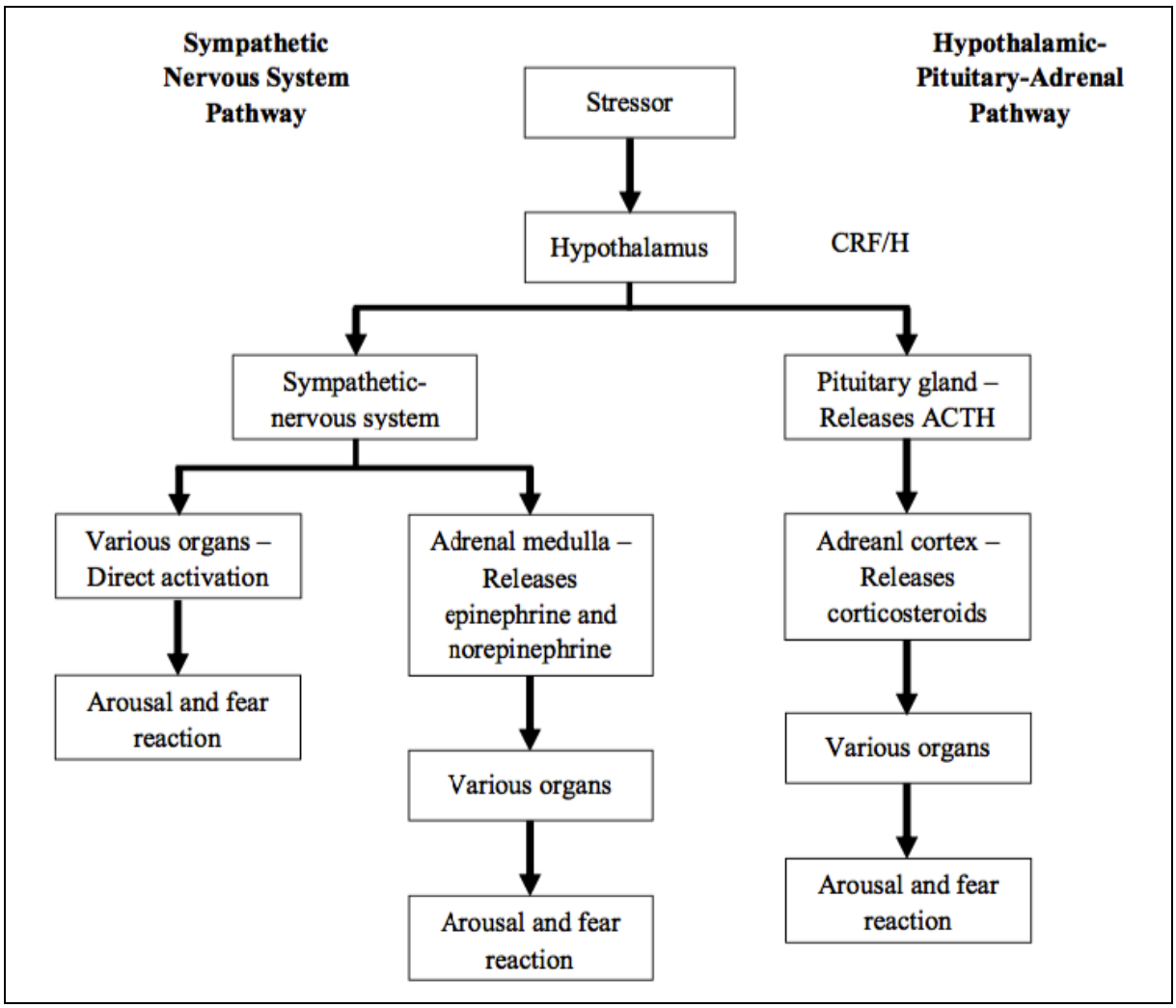

Figure 6: The SAM and HPA axis (Comer et al., 2015)

Due to the fact that we measured and evaluated primarily cortisol levels (a parameter of the HPA axis) in our empirical study the main focus will be on the HPA axis. However, for the principle of completeness the SAM system is subsequently presented in brief.

2.2.1 The fast mode: sympatho-adrenal-medulla system (SAM)

Research on the SAM roots back to the works of Cannon (1929) who taught that stimuli (environmental or internal) that threaten homeostasis concurrently activate the adrenal gland

to release epinephrine (EPI, synonymous adrenaline) and the sympathetic nervous system (SNS) which is part of the ANS. For Cannon and colleagues the two effectors were functioning as a unit and came to be termed “sympatho-adrenal”, “sympathico-adrenal” or “sympatho-adreno-medullary” system (Goldstein & Kopin, 2007). The SAM system is one of the major pathways mediating physiological responses in different organs and tissues in the body. It provides a rapidly responding mechanism that controls most of the acute response of the individual to a stressor (Melmed et al., 2015; Stratakis & Chrousos, 2006). The hypothalamus, in particular the PVN, controls both the SAM and the HPA axis response systems. The PVN synthesizes corticotrophin-releasing hormone CRH and AVP, and secretes via the median eminence into the hypophyseal portal blood (Gore, 2013). The hypothalamus controls the SAM system by stimulating neurons connected to the adrenal medulla and the pons. These in turn activate the ANS producing the “fight or flight” response which stimulates the SNS while inhibiting the parasympathetic nervous system (PNS) (Tsigos & Chrousos, 2002). One approach of the SAM system to regulates the body’s stress response is by stimulating the cardiovascular system. To ensure sufficient oxygen and energy in the brain as well as in the skeletal muscles for the “fight or flight” response, the heart rate is increased and the blood vessels are constricted in diameter. Interindividual differences in the stress response occur depending on former experience of the individual as well as the interpretation of the situation (Melmed et al., 2015).

2.2.2 The slow mode: hypothalamic-pituitary-adrenal axis

The other peripheral limb of the stress system which is working cooperatively with the SAM system is the hypothalamic-pituitary-adrenal (HPA) axis. Its key role in maintaining homeostasis is long known and the HPA axis bas been the subject of intense and longstanding scientific research.

2.2.2.1 Functioning and hormones of the HPA axis

The HPA axis is a regulatory system that intricately interconnects the CNS with the periphery via hormonal signaling and involves communication between the hypothalamus, the anterior pituitary gland, and the adrenal cortex within the adrenal gland (Melmed et al., 2015). It consists of the PVN, pituitary (glandula suprarenales) and the adrenal glands which lie on top of the kidneys and compose of the adrenal medulla and the adrenal cortex. While the smaller inner adrenal medulla synthesizes EPI and NE and is involved in the SAM system, the larger and outer adrenal cortex synthesizes corticosteroids: mainly the mineralocorticoids (MC) and the glucocorticoids (GC). The adrenal cortex consists of three zones (the outer zona glomerulosa, the middle zona fasciculata and the inner zona reticularis) and is composed of steroidogenic cells. GC such as cortisol are synthesized in the middle zona fasciculata, while MC such as aldosterone are synthesized in the outer zona glomerulosa. The inner zona reticularis synthesizes the androgen dehydroepiandrosterone (DHEA) which, among other functions, is a precursor to testosterone and oestrogen. While GC exhibit a multitude of functions affecting metabolism, immune function, and the central nervous system, MC's such as aldosterone maintain normal blood volume, promote water and sodium retention and increase urinary excretion of potassium. The corticosteroids cortisol, aldosterone and DHEA, are all synthesized from cholesterol in the adrenal cortex. Both cortisol and DHEA are major stress hormones with effective responses to the stress stimuli in many body tissues including the brain (Lennartsson et al., 2012).

Therefore, the hormones of the HPA axis are primarily CRH, ACTH and Cortisol. CRH is a 41 amino acid peptide expressed in the hypothalamus (Gore, 2013). CRH neurons project to the external layer of the median eminence, where peptides are secreted into the portal bloodstream through which they are transported to the anterior pituitary. In addition to CRH, CRH neurons express and release AVP, although most AVP is express in neighboring magnocellulare elements of the PVN. CRH and AVP show a positive reciprocal interaction, with CRH being the principal hypothalamic regulator and AVP having potent synergistic effects in adrenocorticotrophic hormone (ACTH) and beta-endorphins ACTH secretion (McEwen et al., 2015a; Volpi et al., 2004). CRH and AVP travel through the infundibulum to the anterior

pituitary, where proopiomelanocortin (POMC) is synthesized and decompose it into ACTH and beta-endorphins (Dedovic et al., 2009). The polypeptide hormone ACTH in turn stimulates the adrenal cortex, resulting in the synthesis of glucocorticoids, mainly cortisol in humans, in the zona fasciculate of the adrenal cortex (Molina, 2006). Due to the importance of cortisol for this project cortisol will be focused on in greater detail in chapter 3.2.4.

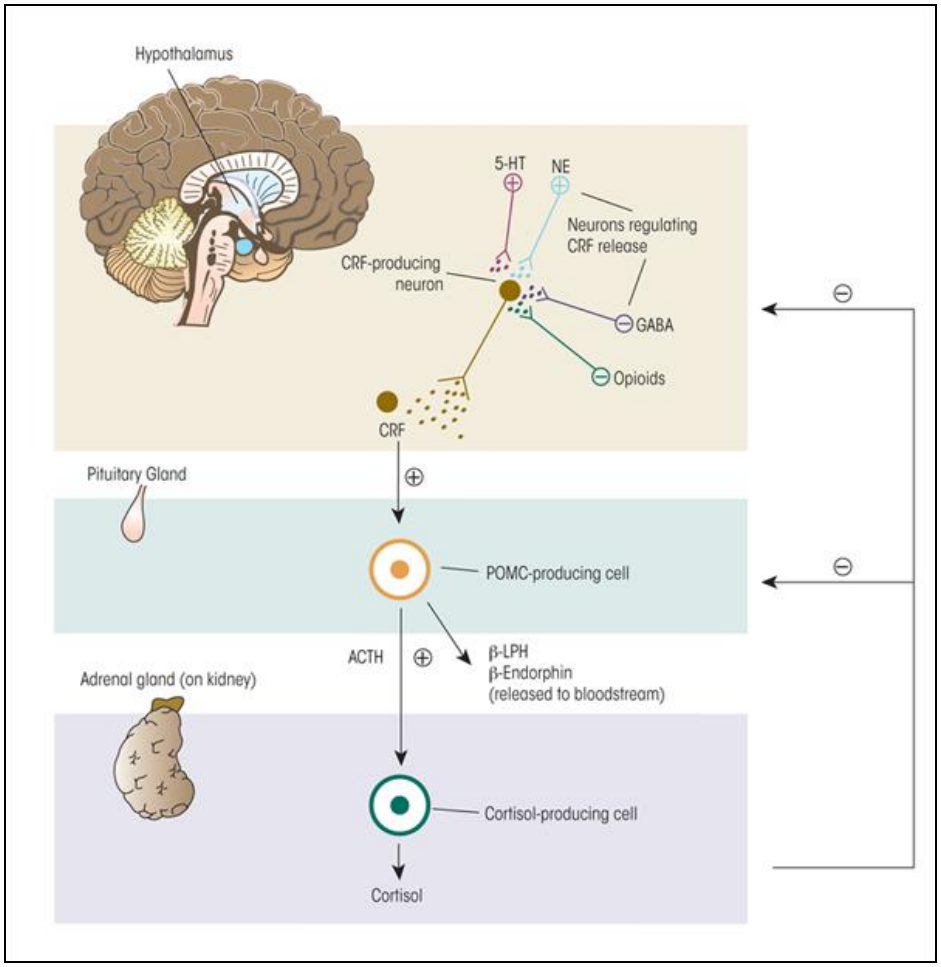

Figure 6: Major components of the HPA axis (Stephens & Wand, 2012)

2.2.2.2 Activation and regulation of the HPA axis

The HPA axis is not simply an alarm system activated by potentially harmful or excessively demanding stimuli, but has two distinct modes of action. Firstly, under unstimulated basal

conditions it follows a diurnal release pattern, with peak levels of glucocorticoids linked to the start of the activity phase upon awakening. Throughout the day the levels decline and are mostly lowest at the end of the activity phase, after which levels begin to rise anew (Gore, 2013). It is assumed that the release of glucocorticoids is under control of an endogenous biological timekeeper, the circadian clock, that acts to prepare the organism for daily challenges (Dickmeis, 2009). Circadian control of glucocorticoid production as well as secretion involve a central pacemaker in the hypothalamus, the suprachiasmatic nucleus, as well as a circadian clock in the adrenal gland itself. Therefore, the HPA axis and the ANS mediate this central circadian regulation, while the adrenal gland clock appears to control sensitivity of the gland to the ACTH (Dickmeis, 2009). Concentrations of ACTH show similar, but less pronounced, fluctuations (Gore, 2013). Secondly, while basal activity of the HPA axis oscillates, the system is activated under emergency conditions through neuronal input. A prototypical neuroendocrine response to an acute psychosocial stressor involves various hormones in a most consistent manner (Sapolsky et al., 2000). After sensory information has been evaluated in the limbic system (hippocampus and amygdala) and been appraised as a threat catecholamines are released from the sympathetic system, and neurons in the PVN of the hypothalamus release CRH and AVP into the hypophysial portal blood. Then, in a second step both hormones stimulate the anterior pituitary gland to produce and secrete ACTH into the general circulation. ACTH in turn induces glucocorticoid synthesis and release from the adrenal glands. The hormones of the first wave exert most of their effect on target tissues within a few minutes, while the majority of GC effects are not exerted until about an hour after the beginning of the stressor. When cortisol levels reach a certain level, CRH and ACTH release diminishes (Stephens & Wand, 2012).

To protect against an exaggerated HPA stress response which could have deleterious effects to the individual the HPA system is carefully modulated through several negative feedback loops (Stephens & Wand, 2012). There is a “short” feedback from the pituitary to the PVN of the hypothalamus (ACTH signaling back inhibiting further release of ACTH) as well as to the PVN (cortisol inhibiting further release of CRH) and two “long” feedbacks from the adrenal cortex to the pituitary (cortisol inhibiting further release of ACTH) as well as to the PVN (cortisol inhibiting further release of CRH) (McEwen et al., 2015a). It is obvious that this is a

simplification of the complexity with numerous further affecting factors (i.e. signaling from the limbic system or the influence of the SAM system in the adrenals) (Melmed et al., 2015). Furthermore, the prefrontal cortex (PFC) (Kern et al., 2008) and the hippocampus with its various connections to the hypothalamus have inhibitory effects on CRH neurons in the PVN (Buchanan et al., 2009).

2.2.2.3 Modulating variables of the HPA axis

Different variables have been identified that may influence basal as well as stress associated HPA axis activity. Firstly, the forementioned circadian rhythm of the HPA axis which is explained by a direct connection between PVN and nucleus suprachiasmaticus is to be mentioned maybe the most obvious modulating variable. While a clear circadian periodicity could be found for the HPA axis related hormones (CRH, ACTH and cortisol) this differs in clinical populations – for example for patients with stress-related disorders (Ehlert et al., 2001; Frodl & O'Keane, 2013). Especially well explored are the increased cortisol levels in patients with major depression (de Kloet et al., 2005). Furthermore, there is very strong evidence that the HPA axis is strongly activated in situations of psychosocial stress with elevated cortisol levels increased after stress (Kudielka et al., 2003). Kirschbaum and Hellhammer (1999) as well as Kudielka et al. (2009) reported other modulating factors such as gender, age, consumption of nicotine, the phase of the menstrual cycle, pregnancy, excessive sport, genetic disposition, intake of exogenous hormones (e.g. oral contraceptives), endogenous hormones (e.g. sex steroids) as well as others that may interfere.

2.2.2.4 Cortisol: A marker for HPA axis activity

Cortisol is a key player in the HPA axis stress response and a lipophilic glucocorticoid. Cortisol peaks in the morning and decreases over the day. It has a pulsatile secretion with about 7-15 surges per day and as with all corticoids cortisol is synthesized from the precursor cholesterol via specific enzymatic systems. The synthesis is induced by the activation of the HPA axis (see 3.2.2.1) and it constitutes for 95% of all glucocorticoids in humans (Kallen,

2004). As cortisol is a steroid and lipophilic most of it binds to transport proteins in the bloodstream after release from the adrenal cortex. Approximately two thirds of the released cortisol in healthy adults binds mostly via high-affinity receptors to the corticosteroid-binding globulin (CBG) (Molina, 2006). Around 15 to 20 per cent bind via low-affinity receptors to albumin, while another 5 per cent binds to erythrocytes and only around 0.1% to testerone-binding globulin. Therefore, only 5 to 10 percent of unbound, free cortisol circulates and can be considered as biologically active (Melmed et al., 2015). The cortisol binding proteins act as a pool, releasing unbound cortisol into the plasma as soon as the free cortisol concentration decreases. Due to its lipophilic nature, unbound cortisol may diffuse easily through cell membranes and distribute widely throughout the body. Cortisol transfers passively into saliva as a filtrate from the blood and is able to travel across the blood-brain barrier. Therefore it is found in the cerebral spinal fluid (CSF) and may reach the amygdala, hippocampus, hypothal-amus, and anterior pituitary (Molina, 2006). The unbound fraction of cortisol may be assessed in urine, blood as well as saliva. Urinary-free cortisol (UFC) is often assessed over a 24-hr period and is thought to reflect the amount of cortisol released by the adrenals that is released over a complete circadian cycle (Yehuda et al., 2003). Collection of cortisol from the plasma requires only minor invasive blood collection, while the collection of cortisol from the saliva is completely non-invasive by simply chewing on a cotton swab (e.g. Salivette©). Fortunately, measurements in the blood and saliva correlate highly (Hellhammer et al., 2009). Yehuda et al. (2003) have pointed out that advantages of saliva assessment lie in the non-invasiveness, the convenience of the procedure for the participants as well as that the collection can be done at frequent intervals and does not require medical personal or special storage. These may be the reasons that it has become the “gold standard” to exploring stress reactivity and is also ideal for naturalistic studies. In both measurements, saliva as well as blood, cortisol levels are analyzed with radioimmunoassay.

The role of glucocorticoids lies in numerous processes of the metabolism as well as in the interaction with the immune system, the circulation and regulation of electrolytes (Ehlert, 2003). Specifically, GC influence the lipometabolism, carbohydrate as well as the protein metabolism all of which are of eminent importance for managing stressful situations. In particular is cortisol responsible for glucogenesis in the liver and therefore the allocation of

energy in the stress reaction. In the brain they exert a broad range of molecular, structural and functional effects through MC and GC receptors (de Kloet et al., 2008). GC can also exert immediate effects of the activation of receptors as well as long-lasting programming effects on brain function and behavior (de Kloet et al., 2008, Sandi & Haller, 2015).

The stress response with the resultant activation of the HPA axis is meant to be acute or at least of a limited duration and while increases in cortisol can be essential for short term survival, prolonged exposure can lead to serious metabolic, immune and psychological dysfunction (McEwen, 2016; McVicar et al., 2013). While the activation of the stress response leads to anti-reproductive, antigrowth, catabolic and immunosuppressive effects such are, if time-limited, rather beneficial than damaging. However, chronic dysregulations of glucocorticoid levels may lead to the syndromal state that Selye described in 1936. The prototypic example of chronic hyperactivation of the stress system is manifested in depression with dysphoric hyperarousal and relative immunosuppression (McVicar & Clancy, 2011). In addition a spectrum of other conditions may be associated with increased and prolonged activation of the HPA axis. These may include cardiovascular diseases, autoimmune disorder, drug use or anxiety disorders (Ehlert et al., 2013). Very intense dysregulations of glucocorticoid levels may also lead to hypo- or hypercortisolism. In case of an atrophy or hypertrophy of the adrenal cortex it's functioning may be effected. Addison's disease is a primary adrenal insufficiency which is characterized by a strongly reduced secretion of hormones and consequently a deficiency of cortisol. By contrast Cushing's syndrome may be a result of hypercortisolism. It induces hypertension, heightened blood glucose levels, adiposity, depression or cognitive disturbances (de Kloet et al., 2005; Zhang et al., 2012).

Already early investigations indicated that psychosocial stress activates the HPA axis (Mason, 1968). With the onset of a psychosocial stressor, the HPA axis is activated and cortisol increases may be measured. On average cortisol peaks after around 15 to 20 minutes after the onset of stress. Around 60 to 90 minutes after the stress reaction hormone concentrations are back on their baseline level (Dickerson & Kemeny, 2004). Unlike the SAM system which has an instant and relatively short lived effect, the HPA axis takes longer and the effects last longer. The HPA response is often comparable, but there are individual differences in the

threshold for HPA activation which have been suggested as being due to a person's predisposition (Jones & Bright, 2001). However, the HPA axis has proven to be a valid system for research on the stress response.

3 Making stress tangible: measuring indicators of stress

It has been shown that stress is a complex phenomenon and that the popular ideas regarding the underlying mechanism not always coincide with the biological reality. Understanding the fundamental concept is an important cornerstone of the field, but it is equally important to being able to measure indicators of the stress response both on a psychological as well as on a biological level. This knowledge may help deepen the understanding of the subject as well as testing different intervention methods, not only for themselves, but in the future maybe also in different populations in order to find the population-centered most effective coping method.

3.1 Levels of stress reaction

It has been shown that the stress reaction may be seen as a holistic response of an individual, where the psychological aspects are inseparably intertwined with the physiological processes. This is the case for all humans, but there are interindividual differences on what level the stress response is being activated. While some may react with their cardiovascular system, others may show muscle tenseness or changes in the digestive system. Kaluza (2004) argues that this individual reaction-specifity may be the result of the interaction of hereditary factors with biographic experiences. An example may be a genetic disposition to cardiovascular hyperreactivity in combination with a certain coping strategy that may lead to overactivation of the cardiovascular system in challenging situations (Kaluza, 2004). The stress reaction may evoke a response on one or several of the four levels:

Table 2: Level of stress reaction (Kaluza, 2007)

Level of stress reaction	Examples
Cognitive emotional level	Thoughts and feelings that may be triggered in a situation. (e.g. feelings of agitation, anxiety, anger, guilt feelings or thought pondering)

Behavioral level	Perceivable behavior that is shown by the individual under the impact of stress (e.g. doing activities hastily, substance abuse, bodily restlessness, petulant interaction with social environment)
Vegetative-hormonal level	Reactions of the ANS and the related physiological systems (e.g. cardiovascular symptoms, immune deficiency, menstrual cycle dysregulations)
Muscular level	Reactions in the realm of the skeletal muscles (trembling, bruxism, backache or tension headache)

Oftentimes these reactions are reinforcing each other leading to amplification of the stress reaction. However, this reciprocal influence may also be utilized to favorably influence the reaction and therefore attenuate it. For Kaluza (2004) it helps individuals in coping if they have knowledge towards what reaction pattern they are prone to under stress.

3.2 Stressors

In the preceding chapters it has been argued that there is an inextricabe entangled relationship between the stimulus in the environment and the individual's interpretation of it. Following a popular expression, it might be said that "stress lies in the eye and appraising of the beholder". Consequently, there are a myriad of possibilities of stimuli that may potentially be experienced as stressors. Yet, there are situations and events that lead with a high probability to a stress response within a large part of the population. Already Mason (1968) suggested that situations that are perceived as particularly intense are: a) meaningful, b) novel, c) unpredictable and d) uncontrollable to the individual. However, as it is an individual appraisal process there is no set definition or categorization of stressors. Nevertheless a distinction between psychological and physical stressors that are either acute (minutes to hours) or chronic (days to months) seems reasonable. And furthermore, for scientific purposes stress

may also be categorized in either natural stressors or experimentally induced stressors (Ehlert et al., 2013).

3.2.1 Acute physical stressors

A wide variety of acute physical stressors have been used in stress response studies in humans. For the sake of completeness a variety of such physical stress tests are reported. They range from resistance and aerobic exercise to cold pressure and sauna exposure. They are described in Table 3.

Table 3: Acute laboratory physical stressors

Stressor	Description
Resistance exercise	A resistance exercise task involving 4 sets of 10 resistance maximum of four different exercises (back squat, bench press, bent over row, and shoulder press). Rest between each sets (Kraemer & Ratamess, 2005).
Aerobic exercise	An 8-minute sub-maximal exercise test on a cycle ergometer. Participants cycle at workloads of 60 up to 180 workloads (Ring et al., 2005).
Cold pressor	Immersion of one hand in 0 - 4^0C water for 60 seconds (Bullinger et al., 1984; Duncko et al., 2009).
	Immersion of one hand in 0-4^0C for a maximum of 3 minutes (Schwabe et al., 2008).
	The immersion of one hand in 10^0C water for 4 minutes exact followed by the immersion of the other hand for 4 minutes exact (Ring et al., 2000).
Cool room exposure	40 minutes in a cold room at 10^0C (Chatterton et al., 1996).
Sauna exposure	40 minutes in a sauna at 66^0 C (Chatterton et al., 1996).

Concurrent with the research objectives of evaluating methods for psychosocial stress the focus will shift to acute psychological stressors and how effects may be monitored.

3.2.2 Acute psychological stressors

Acute psychological stressors have been used in natural as well as experimental settings. Natural settings may be school examinations, daily hassles or important personal events such as marriage, birth of a child or in very burdensome situations traumatization (e.g. sexual abuse, accident in a vehicle) (Ehlert et al., 2013). An advantage of experimental settings is the possibility of standardization and therefore ensuring that the situation for each individual is as similar as possible. As the study follows the research protocol of Gaab et al. (2003) the reported study takes place in an experimental setting and the focus shall be on this group. A wide variety of standardized stress have been used and include mental arithmetic task, stroop color word conflict test, stressful video games, viewing of negative emotional pictures or the Trier Social Stress Test (TSST). In table 4 they are presented in overview.

Table 4: Acute laboratory psychological stressors

Stressor	Description
Mental arithmetic task	A four minute task of mental arithmetic performed according to a strict set of rules (Fredrickson et al., 1991).
Stroop Test	Creating mental processing conflicts in which the words of the colors (blue, red, yellow, and green) are printed in incongruent colors. The task is to ignore the meaning of the word and name the color of the print (Fredrickson et al., 1991; Stroop, 1935).
Stressful video game	Computer game where the game objective is to kill as many enemy characters as possible. The game layout took on a first person perspective ("shooter perspective") which provided a level of virtual realism (Skosnik et. al, 2000).
Viewing of negative emotional pictures	A set of pictures derived from the International Affective Picture System (IAPS). Pictures are divided in four categories, depicting neutral items to extremely negative emotional images. Then participants rate the emotionality of the picture (van Stegeren et al., 2006).

Viewing of a harsh video	Participants are watching a video showing bloody dental procedures, such as the extraction of front teeth and removal of a molar with a pick (Bosch et al., 2003).
Trier Social Stress Test	A psychosocial stress test in which the participants performs a speech and then a mental arithmetic task in front of panel (Kirschbaum et al., 1993).

Psychological stress is capable of activating the sympatho-adrenal-medullary (SAM) system as well as the hypothalamic-pituitary-adrenal (HPA) axis. A meta-analysis of 208 acute laboratory studies (Dickerson & Kemeny, 2004) found that the psychological stressor with the most substantial cortisol response is the Trier Social Stress Test (Kirschbaum et al., 1993) which involves a public speaking as well as an arithmetic task. Already during the preparation for the speech physiological measures such as epinephrine, norepinephrine and cortisol increase in participants (Ehlert et al., 2013). The TSST incorporates elements of uncontrollability and social evaluative threat which leads to a reliable activation of the stress system, which is accompanied by psychological tension in participants (Campbell & Ehlert, 2012). Since its introduction in 1993 the TSST has become a popular laboratory stressor and may be seen as the "gold-standard" in the evaluation of psychosocial laboratory stress.

3.2.2.1 Physiological changes in response to a stressor

Summarizing the preliminary findings it may be concluded that the physiological response to a stressor may be evaluated in the SAM system as well as the HPA axis. In the former the stress respons is to change activation of the cardiovascular system. In particular an increase in heart rate is a common measurement in assessing the SNS stress response. However, activation of the SNS may also result in increased systolic and diastolic blood pressure and are also common measurements in assessing the impact of the SNS in the stress response. Another indicator is the salivary protein alpha-amylase which has shown to be sensitive to psychosocial stress tests and increase. Physiological changes in the parasympathetic nervous system have historically utilized urine or serum and more recently saliva. Physiological changes in the HPA axis in response to a stressor may be measured in saliva cortisol.

3.2.2.2 Psychological changes in response to a stressor

Aside the physiological changes that may be assessed, the subjective experience of stress may be measured with various psychometric instruments. They may focus on different periods of time and different areas of perception or behavior. Over the last century clinical psychological science has been very interested in disease processes (Ehlert, 2003). The focus lies on the negative aspect in a challenging situation and to what extent this is measurable. The following areas have been under scrutiny in research projects (Gaab et al., 2003; Nedeljkovic et al., 2012; Storch et al., 2007):

Depressive symptomatology

Depressive symptoms are among the most prevalent symptoms. In healthy populations questionnaires are utilized that assess f.e. depressive affect and negative thought patterns. Measured characteristics may include insecurity, hopelessness, exhaustion, self-devaluation, loneliness, sadness, anxiety or social withdrawal. An example is the Center for Epidemiological Studies Depression Scale by Radloff (1977), with the german version by Hautzinger and Bailer (1993).

Perceived level of stress in life

The perception of "stress" and which situations in life were perceived as stressful is a focal point of interest. Aspects may be to assess how predictable, uncontrollable, and overloading participants perceive their lives. A common instrument is the Perceived Stress Scale (PSS) by Cohen and Williams (1988).

Disposition to cope with stressors

It also has been of interest on how individuals cope with stressors and specifically what disposition underlies individual differences in physiological and psychological stress responses. It has been assumed that perceived stress reactivity is relatively stable across situations, over time and response systems (Schlotz et al., 2011). The individual's perceived typical response intensity aggregated across different potentially stressful situations in everyday life has been operationalized in the Stress Reactivity Scale by Schulz et al. (2005). A question-

naire that is specifically recommended as a tool to evaluate this area in stress management programs.

However, these aspects are only one part of the process. It is an accomplishment of Antonovski who diametrically changed the approach and focused on what keeps individuals under adverse circumstances healthy (Ehlert, 2003). This may be considered as measuring aspects of resilience or as Antonovsky has put it "sense of coherence". Therefore, psychometric measures of this realm should be part of measuring the process of challenging situations as well. Areas of interest have been (Gaab et al., 2003; Nedeljkovic et al., 2012; Storch et al., 2007):

Generalized resistance resources

It has been proposed that individuals generally possess resistance resources that assist them in coping with a wide variety of life's challenges (Antonovsky, 1987; Kenne Sarenmalm et al., 2011). Such resources may explain why some individuals cope successfully with even severe stressors and remain able to maintain psychological health whereas others do not. A concept has been shown to capture such resistance resources has been termed sense of coherence (SOC). Antonovsky (1987) found that SOC is a resource that enables people to reflect upon their resources (internal and external) and how they can mobilise them to find solutions and resolve tension (Eriksson & Lindström, 2006). A common psychometric instrument to measure this concept is the SOC-L9 (Schumacher et al., 2000).

Self efficacy and competence

Self-efficacy is seen as a central predictor of intentions and behavior. Individual perceptions of own competencies and power (i.e., self-efficacy) is connected to the actual capacity to act autonomously and efficiently (Greve et al., 2001). Perceived self-efficacy is the belief that a novel or difficult task may be successfully coped with. Perceived self-efficacy may facilitate: goal setting, effort investment, persistence in face of barriers or recovery from setbacks (Schwarzer & Jerusalem, 1995). A scale that assesses a general sense of perceived self-efficacy is the Self Efficacy Scale (German: Selbstwirksamkeitserwartung, SWE). by Schwarzer and Jerusalem (1995). Furthermore, the development of personal action compe-

tence is seen as an important prerequisite to succeed in social life and is central to a person's self-regulation of the own development (Brandstädter, 1998). It may be evaluated by utilizing the Questionnaire for Competence and Control Orientations (German: Fragebogen zur Kontrollüberzeugung und Kompetenzerwartung (FKK)).

The quest to measure stress scientifically on different levels and gain better insight into the process as well as being able to compare results with other research groups is a current objective of scientific projects.

4 Stress Management

The negative impact of stress often has encumbering effects on an individual level but also leads on a macrolevel to substantial economical consequences. The symptoms and disorders associated with it that are found on the microlevel have in detail been discussed in the introduction. However, the suffering of the individual and his environment is never fully quantifiable. The economic perspective has been subject to research in the past. For Switzerland, the Swiss State Secretariat for Economic Affairs (SECO) found in a 2010 study that 34% of the swiss working population felt “often to very often” stressed (Grebner et al., 2011). Compared to a previous study by the SECO ten years earlier (Ramaciotti & Perriard, 2003) this number increased by approx. one third during this time. Meanwhile the amount of people that felt “never or sometimes” stressed diminished in the same period (Grebner et al., 2011). Assessing the economic impact of stress is complex as the detrimental effects of stress have impact on many levels. Impaired physical and mental functioning, work days lost, increased impairment at work are just a few effects stress may have. The most recent study regarding the economic impact of stress is from Ramaciotti and Perriard (2003) and estimates the cost of direct (medical costs, self-medication and absenteeism) and indirect (work related accidents and occupational diseases) costs at approximately 8 billion CHF or 2.3% of the gross domestic product (GDP).

Therefore, the urge to find solutions that enable the management of stress and lead healthier lives has been enforced from individuals, organizations as well as governments. This has led to a plethora of methods claiming to counteract the negative dynamic process of stress. Such interventions have been developed over the last 40 years to ameliorate the negative effect of stress (Esch et al., 2007). Approaches that help to relief and cope with stress have been termed and characterized as stress management techniques. Stress management approaches consist of various elements that are usually applied in combination with each other.

4.1 Intervention types of stress management

The general goal of stress management interventions lies in fostering psychological as well as physical health by improving the individual competences of coping with stress. According to Kaluza (2014) it should not be about teaching a standard strategy for a specific stressful situation but to develop strategies built on a variety of approaches that lead to flexibility in coping with daily hassles. The author proposes three approaches to be specifically helpful in a stress management program: a) instrumental stress management, b) mental stress management and c) palliative-regenerative stress management.

Table 5: Strategies of individual stress management (Kaluza, 2014)

Stressmanagement	**Approach**	***Examples***
Instrumental	• Reduce or eliminate sources of stress • Reactive towards existing strains • Proactive planning of favorable circumstances and settings	• Reorganization of working space • Change of working procedures • Use of time management tools • Setting of personal and business goals
Mental	• Reduce malign and stress amplifying personal attitudes and thought patterns • Build helpful and advantageous appraisal processes and thought patterns • Make conscious and critically reflect detrimental thought patterns and transformation into beneficial thought patterns and attitudes	• Critically reflect perfectionist performance demands and learn to accept personal boundaries • Perceive difficulties not as threat but as a challenge • Identify less with daily tasks and keep more inner distance • Become aware of the positive, pleasant and feel thankfulness
Palliative-regenerative	• Address the physical and psychological stress reaction to ease physical tension, inner restlessness and nervousness • Build inner strength and resilience to cope with potential stressors	• Learn a relaxation technique and regular use of it • Develop physical exercise routines • Learn to enjoy the small things in daily life • Maintain a work-life balance by pursuing leisure activities • Use sufficient sleep as a regenerative source

There are various methods to categorize the different approaches of stress management methods. Van der Klink et al. (2001) distinguished four intervention types: cognitive–behavioral approaches, relaxation techniques, multimodal interventions, and organization-focused interventions. While cognitive–behavioral approaches aim at changing cognitions and amplifying existing and new coping skills, relaxation techniques focus on physical or mental relaxation as the method of coping with stress. Multimodal interventions emphasize the acquisition of both passive and active coping skills, while the last intervention type involves a focus on the organization as such. For Esch et al. (2007) the constituents of professional stress management strategies typically consist of nutrition, exercise, behavior (cognitive behavioral interventions, positive psychology) and relaxation (f.e. autogenic training, progressive muscle relaxation) or mild meditative movements (f.e. Yoga or Qi Gong exercises). A more elaborated segmentation of stress management methods has been utilized by Lehrer et al. (2007): a) Muscle relaxation (f.e. progressive muscle relaxation), b) Hypnotic methods (Hypnosis, autogenic training method), c) Biofeedback (Neurofeedback, biofeedback training to increase heart rate variability), d) Breathing retraining and exercise, e) Methods based on eastern meditative and therapeutic disciplines (Mindfulness meditation, Qigong, Yoga, Tai Chi), f) Cognitive methods (Cognitive approaches, stress inoculation training) and g) other methods (Music therapy, eye movement desentization and reprocessing).

Summarizing, it may be stated that as stress is a complex multifactorial process there are various strategies that might prove to be helpful to successfully manage it (Folkman, 2013; Regehr et al., 2013). However, to be effective and efficient in its purpose a professional stress management intervention relies on scientific evidence and continuously develops through implementation of the results found in rigorous examination of it. While in the early 20th century the opinion of an authority was the important criteria to decide whether an intervention was improving the condition this relying on clinical experience, clinical instinct and intuition are not sufficient any more. Unsystematic observations may deliver cues as to where to research more, but are not the method of choice to evaluate the efficiency and efficacy of an intervention. There are several limitations to this procedure such as “post hoc non est propter hoc”, meaning “after is not because of” or cognitive biases on both professional (f.e.

"Positivity bias towards the treatment") as well as patient side ("Positivity or negativity bias towards the results") that may confound such observations. The gold standard to assess effectiveness and efficiency of interventions today are randomized controlled trials (RCT). RCT's are not perfect per se and strengths as well as weaknesses give sometimes rise to discussions regarding the validity of the presented results. And while the biologist Jakob Johann Baron von Uexküll might have been right with his, at least to him attributed quote, that "the science of today is the error of tomorrow" RCT's are still the relevant standard to answer the aforementioned question.

Cognitive behavioral stress management interventions are among the best evaluated programs and have shown to fulfill RCT standards (f.e. Abelson et al., 2014). Methods based on eastern meditative and therapeutic disciplines have in the past years been used more frequently. To some extent they have been evaluated, for example Yoga (Kiecolt-Glaser et al., 2010) or Tai Chi (Nedeljkovic et al., 2012), but for many methods there are no RCT's published yet. A method that is also based in the category of "eastern disciplines" and is commonly used as well as recognized by the Swiss government as an accredited profession, is kinesiology.

4.2 Cognitive Behavioral Therapy and Stress Management

In the development of psychology as a field many therapeutic forms with different underlying assumptions and treatment forms have developed. Unified by the core concern of maintaining mental health or the restoration of healthy functioning among the recent and most widely used intervention methods are those based on cognitive and cognitive behavioral strategies (Hofmann et al., 2012). Historically the incorporation of cognition in behaviorally dominated clinical psychology era was a gradual shift rather than an abrupt change. The antecedents of cognitive therapy were the social learning theory of Bandura (1969) and Mischel (1973) who suggested the importance of cognitive variables and placed these within the context of "covert behavior". This context allowed them access to "legitimate" scientific status (Ingram et al., 1991). According to Ingram et al. (1991) the group among which the term *cognitive-behavioral* was used first, consisted of Beck (1976) and Ellis (1963) which came from

traditions that were not originally behaviorist, as well as Kendall and Hollon (1979), Mahoney (1974), Lazarus (1981) and Meichenbaum (1977). Currently the *cognitive behavioral approach* consists of cognitive-behavioral therapies and interventions that share a core set of assumptions and characteristics. While there are such unifying elements that constitute the approach it is important to state that by no means it is a uniform or single approach of treatment. There are meaningful differences among specific cognitive-behavioral interventions (Ingram et al., 1991). The core characteristics of any treatment considered to be cognitive-behavioral are a) cognitive variables are assumed to be important causal mechanisms. There may be other meaningful causal mechanisms as well, but cognitive variables are important in the constellation of processes that elicit the onset and course of a disorder and b) following from the assumption that cognitive variables are presumed to be causal agents, at least some of the methods and techniques of the intervention are aimed specifically at cognitive targets (Ingram et al., 1991). Certainly, there are many more shared assumptions and features of cognitive-behavioral methods but the aforementioned are in some form always present.

Butler at al. (2006) report over 325 published outcome studies on cognitive-behavioral interventions. CBT is adapted increasingly to a wider range of disorders and problems (Beck, 1997; Salkovskis, 1996). Exempli gratia are treatment for depression, generalized anxiety disorder, panic disorder with agoraphobia, social phobia, obsessive-compulsive disorder, posttraumatic stress disorder, schizophrenia, anger, bulimia nervosa, childhood disorders, sexual offending or chronic pain (Butler et al., 2006; Hofmann et al., 2012). It is noteworthy, that according to Bodenmann and Gmelch (2009) stress is often prevalent in the etiology of psychological disorders or acts as trigger that sets off an adverse development that may lead to it. Also, stress is an essential factor in the diathesis-stress model of psychological disorders. But as stress and its adverse consequences on health are such important topics, the quest for interventions and trainings that effectively attenuate stress has gained in importance in psychologically based health promotion (Benedict, 2013).

4.2.1 Overview of cognitive behavioral stress management interventions

Cognitive-behavioral stress management (CBSM) contains different approaches aimed at improving the ability to cope and prevent stress. It is geared to positively influence the psychological and physiological stress reaction. A large part of CBSM are based on the transactional stress model by Lazarus & Folkman (1984) and of cognitive therapy (Beck, 1976; Ellis, 1963; Meichenbaum, 1985). Many CBSM programs aim to enhance individual coping with stress, while their emphases are on a) imparting of a theoretical framework of stress, b) identifying and change of stress inducing cognitions, c) problem-solving training and d) elements of relaxation training. In short it could be stated that most programs focus on psychological as well as physiological aspects of the stress process (Riekert et al., 2013).

The CBSM interventions either facilitate approach-specific coping strategies or a combination of various multimodal techniques such as: cognitive restructuring techniques, relaxation, problem solving strategies, coping skills rehearsal, meditation, biofeedback, anger management, breathing techniques, life style changes, self-assertion techniques, scrutinizing one's own values, social support utilization as well as other elements that may be applied. Lazarus and Folkman (1984) conceived stress management as a regulative process, which is triggered by the individual's appraisal of a situation as threatful. Events that initiate this coping may lie within the person (the individuals own overexaggerated demands or setting one's own goals that are too ambitious) or from the outside (demands from others or exorbitant goals from the environment) (Bodenmann & Gmelch, 2009). According to Lazarus and Folkman (1984) the appraisal may initiate a chain of activity and coping actions to manage a situation. Therefore, Lazarus and Folkman (1984) proposed that CBSM intervention programs should include an emotion-focused as well as a problem-focused approach. These are seen as the two main functions of stress management. Problem-focused coping is also known as assimilative and emotion-focused coping as accommodative.

Table 6: Emotion-focused and problem-focused coping

	Description	**Examples**
Emotion-focused coping	Regulate the emotions evoked by the stressful event.	• Distraction • Emotional disclosure (f.e. expressing emotions by talking or writing about those emotions) • Mindfulness and relaxation • Cognitive reappraisal
Problem-focused coping	Problem focused strategies aim to remove or reduce the cause of the stressor (Folkman & Lazarus, 1985).	• Problem-solving • Time management • Obtaining instrumental social support (f.e. supervisor or mentor)

Bodenmann and Gmelch (2009) see those functions not as each other excluding categories but rather such that are complementary to each other and in most cases, are emotion-focused as well as problem-focused strategies necessary to successfully master the challenge. In any case Meichenbaum (2007) suggests that individual and cultural differences should be considered. Further support for individualization of CBSM programs comes from Wortman and Silver (1989) who emphasized that individuals under stress show variability in coping strategies. Therefore, the flexibility of a client's behavioral repertory should be facilitated in the training and not a "one fix for all" standard strategy. As early as 1984 Lazarus and Folkman emphasized that the individual should learn to adapt his coping to a specific situation and conditions as well as goals. Generally the role of cognitive and affective factors in the development and coping of stress are analyzed in CBSM trainings.

4.2.1.1 Validated stress management trainings

Numerous studies have demonstrated that CBSM can effectively influence psychological and physiological parameters and health status in patient populations as well as in healthy individuals (Bodenmann & Gmelch, 2009). CBSM may strengthen existing and build new competences, change appraisal and coping styles, develop new behavior in actual situations,

build a feeling of self-efficacy, psychologically immunize an individual against stress and thereby enhance physiological and psychological well-being. While there are many different CBSM trainings marketed not all have empirically been evaluated and shown to be sufficiently efficacious. Established and empirically validated general CBSM trainings in the German speaking area are the trainings in Table 7.

Table 7: Empirically evaluated group CBSM interventions in German speaking Europe (Kaluza, 2006)

Program	Authors/ Literature	Emphasis/content	Length of time
Successful dealing with daily stresses	Kessler & Gallen; revision by Müller & Kröger (2003)	• Short-term and long-term strategies to successfully cope and prevent stress	• 16 sessions (60 – 90 Min, weekly)
Calm and confident during stress	Kaluza (2004)	• Basic training: relaxation technique, problem solving training and cognitions-training • Supplement: Sports and movement, social support, goal setting, time management and emergency strategies	• 12 sessions (120 Min, weekly, other forms possible)
Optimistically manage stress	Reschke & Schröder (2000)	• Information, clarification, behavior and cognitions analyses of stress relevant circumstances, behavior-modifying exercises and training methods	• 10 sessions (60 Min)
Rationale-emotive group training against stress	Schelp et al. (1997)	• RET-theory and problem understanding, symptom stress, modules regarding emotions, cognitions and behavior	• Depending on target population
Stressinoculation-Training (SIT)	Meichenbaum (2003)	• Psychoeducation, diagnostic of stress relevant cognitions and behaviors, problem solving training, training of coping strategies, stress confrontation	• Depending on target population
SWISSSIT **Swiss Stress Inoculation Training**	Gaab et al. (2003)	• Clarification of general and individual development of stress, identifying of stressors, build-up and reinforcement of stress coping abilities • Specific: adaptation to f.e. patients with HIV	• Depending on target population • Healthy: 2 days (14h) • HIV: 12 sessions (120 Min)

Stressfit – Training for individual coping with stress	Bodenmann et al. (2002)	• Psychoeducation for the topic stress, stress diminishing activities, avoidance of unnecessary stress, dealing with acute stress, health life style	• 1 day (6h)

According to Bodenmann and Gmelch (2009) the stress prevention program by Meichenbaum (2003) is probably the most known scientifically substantiated CBSM intervention. It is also widely used in the German speaking area of Europe.

4.2.1.2 The Stress Inoculation Training (SIT)

In this study an adapted version of the SIT by Meichenbaum (2007) was utilized. SIT is a flexible, individually tailored, multifaceted form of CBSM. The central concept underlying SIT is that of "inoculation". This has been used in biological medicine as well as in psychological research on attitude change. In 1796 Edward Jenner noted that inoculation of humans with cowpox conferred immunity against the deadly smallpox virus. Vaccinations often involves exposure to weaker forms of a disease to ward off more severe reactions (Meichenbaum, 2007). The earlier exposure to a moderate form of the stress or disease shields the body by producing antibodies and physically prepares it for future attacks. This is consistent with the concept of *hormesis* that studies the positive results that derive from exposure to small amounts of toxins that in larger amount might be lethal (Aldwin and Levenson, 2004). SIT is based on the notion that exposing clients to milder forms of stress can bolster both coping mechanism and one's confidence in using the coping repertoire as well as developing a sense of mastery. Given the wide spectrum of stressors that individuals experience, SIT provides a set of general principles and clinical guidelines for treating distressed individuals, rather than a "prescription" formula for a specific situation. It is a semi structured and flexible program combining elements of teaching with classical cognitive behavioral techniques like the Socratic Dialogue, cognitive restructuring, problem solving, relaxation, behavioral and imaginary techniques, self-monitoring, self-instructions, self-reinforcement and environmental strategies. SIT includes a repertory of problem- and emotion-focused coping strategies to

deal with present and with future stressors (Meichenbaum, 2003). The founder of SIT formulated the following general goals of the intervention:

1) inform the client about the transactional character of stress and coping with it,
2) train the client in the perception of dysfunctional thoughts, images, emotions and behaviors in order to reappraise the stressor successfully,
3) to learn the client problem solving and coping strategies,
4) to sensitize the client to use maladaptive reaction as a cue to activate his coping repertory,
5) to conduct behavioral and imaginary exercise and gradual confrontation to reinforce the client's faith in his coping competence, and
6) to help the client gain sufficient knowledge of effective coping and improve his self-awareness and coping strategies when confronted with (un)expected stressors

The program consists of three phases: a conceptual educational phase, a skills acquisition and skills consolidation phase and a practice and follow-through phase. The first phase, also known as *information or conceptualization phase,* is about building a therapeutic alliance with the client and informing about the underlying scientific stress concept. This relationship provides the groundwork that enables and encourages clients to confront stressors and implement the new learned coping skills, both within the training sessions as well as in behavioral in-vivo experiments (Meichenbaum, 2003). The second phase, *the skills acquisition and practice phase,* clients are invited to learn and acquire new coping strategies. If clients already possess helpful stress management skills they are consolidated in this phase. An important focus of this phase is emphasized on guidelines to achieve generalization and maintenance of the treatment effects (Meichenbaum, 2007). The third phase, *practice and follow-through phase,* gives clients the opportunity to apply the new knowledge of coping skills stepwise to increasingly demanding levels of stressors. The phase contains imaginary and behavioral exercise, modeling, role playing, and graded in vivo exposure. Clients explore with the trainer possible high-risk stressful situations and then rehearse and practice in a collaborative fashion with the trainer the coping techniques that might be helpful. Part of the

follow-through and transfer phase is also relapse prevention intervention. Clients learn how to view lapses, that might occur, as “learning opportunities” rather than as occasions to “catastrophize” and relapse. The follow-through features of SIT are designed to extend training into the future (Meichenbaum, 2003). However, the three phases are not meant to be distinct categories but rather overlap.

Meichenbaum (2003) has reviewed numerous studies and showed that SIT is efficacious and efficient in various populations. SIT has been applied in therapy and health prevention with groups, couples or individuals and in clinical as well as non-clinical populations. In casu the SIT was group based, with 18 individuals attending the training sessions on two consecutive days for six hours. A trained therapist and SIT expert led the workshop and instructed the participants.

4.2.2 Empirical evaluation

In a systematic search of published data in PubMed a vast body of literature concerned with the evaluation of CBT as well as CBSM was found. However, when focusing on the empirical evaluation and specific effects of stress management interventions in healthy individuals relatively few studies exist. The accumulation of stress management studies across a wide variety of intervention areas, geographic settings, assessing a multitude of intervention tactics, calls for systematic reviews. Meta-analysis has become the widely-accepted technique for assessing the effectiveness of interventions (Richardson & Rothstein, 2008).

4.2.3 Results from meta-analyses on CBSM with healthy individuals

A systematic review of research revealed that only 11 meta-analyses address stress management interventions with healthy individuals (as located in the database Pubmed: Alzahem et al., 2014; Bamberg and Busch, 1996; Jones and Johnston, 2000; Joyce et al., 2016; Edwards et al., 2003; Kaluza, 2002; Miller and Cohen, 2001; Regehr et al., 2012; Richardson and Rothstein, 2008; Shiralkar et., 2013 and van der Klink et al., 2001). Summarizing the results

of all meta-analyses it may be stated that CBSM with healthy individuals has consistently found to be effective in influencing psychological and physiological parameters as well as health outcomes in health and disease. Kaluza (2002) integrated 36 studies (n = 2133). 22 of the 36 studies were randomized-controlled trials, on average the participants were 36 years old (SD = 12.4) and the preferred intervention groups were students (8), employees in different fields (6), teachers (4) and hospital personnel (3). Mean training time was 13 hours, with a range between 6 and 30 hours, while half of the studies were below 10 hours of training. The training period varied from one day to 28 weeks, with a mean of 7 weeks. In half of the studies examined the program consists of the three building blocks (information, relaxation and cognitive restructuring). The other studies add techniques such as time management, communication, social support, problem solving and information regarding health behavior. Kaluza (2002) found positive evidence regarding the efficacy of the programs in different result categories. He found small (d = 20) to middle-sized (d = 50) effects with the relatively strongest effects shown in the improvement of psychological and physiological wellbeing. It is noteworthy that subjective stress perception and somatic complaints seemed to decrease only slightly. The sustainability of the intervention was evaluated with follow-up measurements and an increase of effect size from 0.54 (for the period < 6 months) to 0.82 for a prolonged period was found. However, only the measures on psychological well-being could be calculated for an observation period of longer than six months. Kaluza (2002) understood this as indication, that training effects do not fluctuate over time but seem to amplify. However, it needs to be noted that because many studies lacked a control group the validity of this conclusion is not certain. The effect sizes found correspond well with the evidence found in a meta-analysis by Bamberg and Busch (1996) on occupational CBSM. Interestingly the less effective interventions proved to be the ones that were rather short seminar-style with emphasis primarily on conveying information. The most successful programs were longer and emphasized the transfer of the new acquired coping skills into everyday life. To evaluate the influence of training intensity on the effects, the effect sizes for the psychological well-being were calculated for short-term (below 10 hours of training) and long-term (more than 10 hours of training) interventions. Thereby, a difference in effect size of 24 points (d = 27 for short-term and d = 51 for long-term) could be observed. This might hint that the length of a program is an indicator of the trainings intensity and might be a

relevant moderator of efficacy. In the meta-analyses Kaluza (2002) criticizes three shortcomings: 1) The methodological shortcoming of missing control groups leads to missing data regarding the long-term efficacy of the interventions and this is a crucial part of the evaluation. 2) The success criteria are skewed towards negative psychological feelings (f.e. anxiety, depressive mood, exhaustion or physical discomfort). Success is than reduced to the reduction of negative states and positive indicators of psychological and physical well-being are not collected. 3) The primary objectives of stress management, the coping strategies utilized after the training are not being evaluated and are not part of the success criterias (Kaluza, 2002). Van der Klink et al. (2001) used meta-analytic techniques to examine the effectiveness of workplace stress management interventions. Forty-five Studies that were published between 1977 and 1996 were meta-analyzed. The authors found significant but small effect size (d = 0.34) and when analyzed CBSM interventions achieved the larges effect size (d = 0.68). However, Richardson and Rothstein (2008) criticize that studies of varying study designs and methodological quality were included. Some did not include control groups while others used only quasi-experimental designs. It was concluded that in their meta-analyses only methodologically strong designs as well as new studies should be considered. Richardson and Rothstein (2008) identified 38 articles (n = 2847) that met the inclusion criteria with sample sizes ranging from 14 to 219 participants and a mean of 49. Of the participants 59% were female and mean age was 35.4. Average intervention length was 7.4 weeks with the mean number of treatment session being 7.5, each lasting 1 – 2 hours. Meta-analysis yielded a significant effect size across all studies (d = 0.52) which by Cohen (1988) is considered as a medium to large effect size. Concurring with the meta-analyses of van der Klink et al. (2001) they found cognitive-behavioral interventions to yield the largest effect sizes (d = 1.16). Despite the stronger effects of CBSM the most popular treatment were relaxation and meditation techniques. The authors hypothesize that it might be the simplicity of the procedure that makes these interventions favored. The authors criticize that only a quarter of interventions of the studies assessed included follow-up measures subsequent to the posttreatment evaluation. Richardson and Rothstein (2008) encourage future research that more methodologically rigorous interventions studies with random assignment to treatment and control groups should be conducted. Another meta-analysis of Regehr et al. (2012) identified 24 studies in peer reviewed journals with randomization or parallel cohort design involving 1431 students. Of

those included in the meta-analysis, 24% of the participants were male. Focus of the analyzed research project had been to reduce stress in university students and reduce resultant anxiety and depression. Their findings suggest that CBSM interventions significantly reduce symptoms of anxiety and depression scores as well as lower levels of cortisol. The meta-review by Joyce et al. (2016) focuses on workplace interventions for common mental disorders and also CBSM in the workplace environment. They identified 5179 articles and 140 studies met the inclusion criteria, of which 20 were deemed to be moderate or high quality. Together, the reviews analyzed 481 primary research studies. The authors concluded that there is evidence that CBSM programs produce significant change in terms of symptom reduction. Among the mention meta-analyses authors there is consensus that the methodological approach should be optimized. For example Edwards et al. (2003) criticize small sample sizes, the lack of follow-up assessments or low response at follow-up, the use of non-standardized measures and inadequate statistical analyses. There seems to be need for rigorously designed studies with randomized-controlled studies with follow-up assessments, which measure specific outcome parameters and include potential moderator variables. In summary it may be concluded that randomized-controlled studies provide empirical evidence that CBSM interventions yield positive results toward psychological and physiological well-being as well as endocrine and immunological functioning.

4.2.4 Effects of cognitive behavioral stress management on physiological and endocrinological aspects

CBSM impacts physiological aspects of the body which have been subject to evaluation studies in various fields. Most studies in this field have yielded consistent results. While Gaab et al. (2003) and Blumenthal et al. (2005) have shown the positive effect of CBSM on the reduction of physical arousal many studies have focused on immunological parameters as well as changes in the hypothalamic pituitary axis.

4.2.5 Results from studies with healthy populations

Antoni and colleagues (1991) evaluated 47 healthy gay men who were randomly assigned to a CBSM condition or an assessment-only control group five weeks before being notified of their human immunodeficiency virus-1 (HIV-1) antibody status. Seropositive did not increase in depression and revealed significant increases in helper-induced (CD4) and natural killer (CD56) cell counts as well as a slight increment in proliferative response to phytohemagglutinin. The authors conclude that psychological buffering and immunomodulating effects of the CBSM manipulation may be attributable, at least in part, to the skills learned and practiced (Antoni et al., 1991). Vedhara et al. (2003) conducted a study with forty-three elderly spousal carers of dementia patients and twenty-seven non-carers. At the end of the CBSM training participants received an influenza vaccination and IgG antibody titers to the vaccine were measured. Immune responses to the vaccine revealed that 50% of carers that attended the CBSM training had a fourfold increase in IgG antibody titers, compared to only 7% in the non-intervention carer group. The authors inferred that that the immune response to influenza vaccination appears amenable to improvement through CBSM training.

The Zurich research group around Ehlert and Gaab conducted a series of randomized studies to show effects of CBSM on endocrine functions and psychological well-being. In a study by Gaab et al. (2003) forty-eight healthy male students were evaluated with the Trier Social Stress Test (TSST) after completing the stress inoculation training (Meichenbaum, 2003). In comparison with the control group the treatment group showed attenuated endocrine response ($d = 0.35$) to the TSST. Hammerfald et al. (2006) belong to the same research group and assigned eighty-three healthy participants randomly to CBSM training or a control condition. Four months after the CBSM underwent the TSST and salivary cortisol responses were assessed before and after the stress test. The treatment group both women and men showed significantly reduced cortisol responses. The study showed that positive endocrine training effects are still observable four months after training and therefore may be seen as long-term effective. Similarly, Gaab et al. (2006) conducted a study with twenty-eight healthy students that were in preparation for an important exam. They were randomly assigned to a four-weekly session of CBSM or a control group. Throughout the period prior to the exam the

participants in the treatment group showed reduced somatic and psychological symptoms. On the day of the exam, groups differed in their cortisol awakening responses, with significantly attenuated cortisol levels in the controls. The authors suggested that the long enduring of stress might have resulted in the inability to mount a cortisol response corresponding to the cognitive appraisal in controls could be a result of a dysregulated HPA axis. However, not all studies have found ameliorated cortisol responses to CBSM and it is indispensable to note such. Holling (1999) performed a study with police officers that underwent a CBSM training over the period of three weeks and found no noteworthy effects regarding cortisol response. However, they found long-term effects (six months and up to two years follow up) in improved relaxation and anger management in trained police officers compared to the controls. McCain et al. (2003) conducted a study with two different stress management interventions (CBSM and social support group training) with 148 HIV positive participants (119 men, 29 women). The research group was unable to find differences in cortisol between the two treatment and one control group.

4.2.6 Results from studies with clinical populations

Chronic diseases like HIV or cancer provide a broad range of repeated severe stressors with impact on immune functioning and disease course. Inadequate coping strategies for psychosocial stress may lead to depressed affect, social isolation, psychiatric problems or impaired immune functioning and possibly accelerated disease progression (Catz et al., 2002). Cruess et al. (2000) conducted a study with thirty HIV-seropositive men that participated in a ten-week group-based CBSM intervention. Cortisol levels and mood were assessed within the session. Pre-session cortisol levels decreased across the 10-week period and were related to decreases in global measures of total mood disturbance and anxious mood. These levels were also associated with decreases in self-reported stress level during home practice. Greater reductions in cortisol during the first three session were associated with more frequent relaxation practice at home. Cruess and colleagues (2000) argue that the findings suggest that salivary cortisol represents an objective neuroendocrine marker for changes in anxiety and distress observed during relaxation training in symptomatic, HIV-seropositive men. Antoni

(2003) demonstrated in his 10-week group-based CBSM intervention and psychoneuroimmunologic (PNI) model for Human Immunodeficiency Virus (HIV) that changes in relaxation skills, cognitive coping strategies and social support may mediate the mood effects of CBSM, and that these mood changes may mediate adrenal hormone regulation indicated by reductions in 24-h urinary cortisol (with reduced depressed mood) and norepinephrine (with reduced anxiety) and increases in CBSM-related changes in production of these hormones may explain, in part, the effects of this intervention on short-term changes in IgG antibody titers to herpesviruses (with increased DHEA-S-to-cortisol ratio), and longer-term changes in lymphocyte subpopulations such as CD8 suppressor/cytotoxic cells (with reduction in urinary noradrenaline output) and transitional naïve CD4 cells (with reductions in urinary cortisol output) (Antoni, 2003). The author concludes that a multi-modal CBSM intervention therefore is associated with alterations in mood, neuroendocrine functioning and immunologic status and may have favorable health implications for HIV infection. Similarly, Antoni and colleagues (2005) found decreased level of cortisol in HIV-positive men after a CBSM training, as well as less depressive mood. It seemed that the intervention may have affected the rate of immune system reconstitution by modifying the stress of symptomatic disease and the intervention might work by decreasing depressed mood and normalizing HPA axis functioning.

A diagnosis of cancer and the following treatments place demands on psychological adaptation. According to Antoni (2013) behavioral research suggests the importance of cognitive, behavioral and social factor in facilitating adaptation during active treatment and throughout cancer survivorship. This supposition forms the rationale for the use psychosocial interventions with cancer patients (Antoni, 2013). A sample of twenty-nine women took part in a CBSM intervention on emotional well-being and immune function in the months following surgery for early-stage breast cancer. The participants were randomly assigned to either receive a 10-week CBSM intervention or a comparison experience. McGregor et al. (2004) found greater perceptions of benefit from having breast cancer to the women in the comparison group. At 3-month follow-up women in the CBSM intervention group also had improved lymphocyte proliferation. The CBSM intervention facilitated positive emotional responses to their breast cancer experience in parallel with later improvement in cellular immune function.

A 10-week group-based CBSM intervention with eighty-five women was performed by Antoni et al. (2009). The women with stage 1 – 3 breast cancer were recruited four to eight weeks after surgery and randomized to either the CBSM intervention or a 1-day psychoeducational control group. The participants in the intervention group evidenced better psychosocial adaptation (lower reported cancer-specific anxiety and interviewer -rated general anxiety symptoms) and physiological adaptation (lower cortisol, greater Th1 cytokine [interleukin-2 and interferon-γ production and IL-2:IL-4 ratio) after their additional treatment compared to those in the control group. The psychosocial effects as well as the cortisol appeared to hold across the entire twelve-month observation period, while Th1 cytokine regulation changes held only over the initial 6-month period. Finally, Antoni and colleagues (2016) investigated relations between inflammatory indicators and distress, negative mood and depressive symptoms in women undergoing primary treatment for non-metastatic breast cancer. They demonstrated in a randomized-controlled trial that women receiving a CBSM intervention vs. a psycho-education showed improved mood, decreased circulating cortisol and reduced leukocyte inflammatory signaling in the first twelve months of breast cancer treatment. Furthermore, they demonstrated better health outcomes up to 15 years later (disease free interval and survival time). While women with greater depressive symptoms after surgery showed significantly greater levels of proinflammatory cytokines (IL-1b, IL-6, TNF-a) in serum. Antoni et al. (2016) also found that negative affect was associated with greater leukocyte proinflammatory and pro-metastatic gene expression.

Further evidence that CBSM may be helpful in the development of diseases stems from rheumatoid arthritis and gestational diabetes. De Brouwer et al. (2016) performed a study with 74 patients with rheumatoid arthritis. The participants were randomly assigned to a CBSM treatment or a control group. 1-week after treatment and at 9-week follow up the TSST was performed. Basal and stress-induced cytokine levels did not differ between the groups one week after treatment, but stress-induced IL-8 levels were lower in patients in the intervention group at the follow-up assessment. The authors hypothesize that immune parameters might be altered after a psychosocial stress task in a population with immune dysfunction. The effectiveness of CBSM on psychological stress and diabetic pregnant women has been evaluated in a randomized-controlled study by Zaheri et al. (2016). Eighty-

eight women with gestational diabetes were randomly assigned to the intervention or control group. In the CBSM group stress significantly decreased two weeks after the training and psychological well-being improved. Furthermore, glycemic control improved as well. Improvement in psychological well-being, i.e. decrease in depression, anxiety and stress may lead to better well-being and glycemic control. Overall it may be concluded that the evidence that CBSM may positively alter physiological and endocrinological aspects when confronted with stress is mounting.

4.2.7 Effects of cognitive behavioral stress management on psychological well-being

A diagnosis of an illness like cancer or HIV and the subsequent treatments is stressful and places high demands on psychological adaptation. It may involve fear of being damaged by adjuvant therapy, not seeing children grow, premature death, and loss of social ties and activities (Stanton, 2006). As described above, evidence suggests that CBSM interventions trigger positive effects on neuroendocrine and immune functioning in healthy and patient populations. Fortunately, these changes in physiological processes are mostly associated with mood improvement.

4.2.8 Results from studies with clinical populations

Proceeding with clinical populations it was shown that positive coping skills, along with a high sense of coping self-efficacy, are associated with stress resistance and better psychological adjustment. Mulder et al. (1995) showed that HIV-infected individuals who used such active coping skills also had fewer symptoms of HIV disease progression than those who did not. Good psychological adjustment, like active coping lead to better resilience and are associated with reduced disease progression. Crepaz et al. (2008) found HIV-infected individuals who received CBSM training showed significant improvement in psychological factors including depression, anxiety, anger, and stress when compared to controls. Antoni et al. (2006b) assigned breast cancer patients to CBSM vs. a psychoeducational group and in the weeks after surgery but prior to the onset of adjuvant therapy the CBSM group showed

medium to large effect size decreases in negative affect (d = 0.33), thought intrusions (d = 1.22), anxiety (d = 0.74), and interpersonal disruption (d = 0.53) while also increasing positive affect (d = 0.31), benefit finding (d = 0.82), and positive states of mind (d = 1.16) for up to one year. Bower and Segerstrom (2004) report four types of benefits observed by patients in a CBSM study with women with early-stage breast cancer and see them as mirroring previous research (McGregor et al., 2004).One type of benefit is a more patient, accepting attitude towards life, including a greater ability to adjust to events that cannot be changed and to take things as they come. The second benefit is a positive change in self-view, specifically a perception of oneself as stronger and better able to manage stress and problems. A third type of benefit is a change in interpersonal relationships, a stronger sense of connection and greater empathy. The fourth type of benefit is a deeper sense of purpose in life and a greater focus on important goals and priorities (Bower & Segerstrom, 2004). While CBSM did not approach these benefits directly, it is conceivable that cognitive restructuring and coping skills training that promote the development of more adaptive coping skills may have helped to towards a more accepting attitude toward life and have been helpful to foster a positive change in self-view. The stronger sense of connection and interpersonal relationships as well as the deeper sense of purpose in life might be attributed to the didactic training in use of social support and enhanced by the expression and support promoted by the group experience.

Collectively these studies provide strong evidence that CBSM interventions during active treatment can reliably modulate indicators of stress, affect and adversity and support positive experiences for extended periods of time.

4.2.9 Results from studies with healthy populations – group training

CBSM has shown to ameliorate various aspects of psychological well-being as has been extensively discussed in the review of recent meta-analyses. Gaab et al. (2003) found that in a randomized-controlled trial of healthy participants the CBSM group had lower stress appraisal, a better self-concept of own competence and higher control expectancies during the standardized stress test TSST. Furthermore, the treatment group showed a reduction in the level of perceived stress in post treatment. Van Rhenen et al. (2005) investigated two short-

term stress management programs one of which was CBSM while the other was focusing on physical exercise and relaxation. Both interventions revealed positive impact on psychological complaints such as burnout, fatigue, anxiety and fatigue both at short-term and at 6-month follow-up. It needs to be noted that van Rhenen et al. (2005) conducted the study unfortunately without a control group. Granath and colleagues (2006) evaluated and compared a CBSM intervention with a Yoga program. The study was performed with 33 participants (26 women and 7 men) that participated 10 sessions of over a period of four months. Psychological and physiological measurement were obtained before and after treatment. Both groups improved during the treatment and there was no significant difference in results. However, perceived stress decreased significantly in CBSM (d = 1.42) and Yoga (d = 0.82) as well as ratings on the stress behavior scale (CBSM d = 1.17 and Yoga d = 0.70) decreased significantly in both programs. Ratings of anger decreased only in the CBSM group (d = 0.75). It is notable that at post-examination cortisol levels increased, although not significantly. In a study by Gaab et al. (2006) students underwent a CBSM during their preparation for an important exam and participants in the randomly assigned CBSM group showed significantly lower anxiety throughout the period prior to the exam. In another study by Keogh et al. (2006) with 209 students that were randomly allocated to a CBSM or a non-intervention control group it was found that students that took part in the CBSM delivered better exam results, heightened motivational scores and a reduction in dysfunctional cognitions and attitudes. Tsang et al. (2013) explored the efficacy of a CBSM training for teachers who experienced mild levels of stress, anxiety and/or depressive symptoms in a quasi-experimental study. The intervention group had significant reduction in depression (d = 0.69), anxiety (d = 0.62) and stress (d = 0.66) when compared with the control group.

4.2.10 Results from studies with healthy populations – internet based training

A newer form of training are technology-based behavioral health programs (e.g., computer or web-based programs). According to Rose et al. (2013) stress management has empirical support, but little data on its efficacy with stressed but healthy individuals that employ such interventions. In a study with 66 healthy participants they evaluated a self guided, multimedia CBSM program which was developed for ultimate use by the National Aeronautics and Space

Administration (NASA). The intervention group was compared to an attention control group that received videos and reading material on stress management. The treatment group reported medium to large effects in perceived stress and increases in control over stress as compared to the control group from pre- to post-assessment in the TSST. Interestingly, the program evaluated is ultra-brief with 6 sessions that last 30 – 45 minutes and the users were very satisfied with it. Another web-based training using CBSM to alleviate stress among employees was evaluated by Mori et al. (2014). In the randomized-controlled study 168 participants enrolled and the training group received CBSM training by a qualified expert and one month of follow-up web-based CBSM homework. The training groups ability to recognize dysfunctional thinking was significantly improved both immediately after training completion (d = 0.37) and after six months (d = 0.33). However, the ability to cope with stress did not improve immediately after training, it was improved after six months (d = 0.37). In another study by Hintz et al. (2015) a CBSM online intervention was assessed with 292 psychology students. The intervention groups had lower levels of stress, depression and anxiety symptoms as well as perceived stress relative to the information-only control group.

It has been demonstrated that the field of CBSM is effective for clinical populations as well as for healthy ones. While one-to-one and group-setting have been the most prevalent in the past it may be expected that the digital revolution will leave its mark also in this field.

4.3 Kinesiology

Recently a growing field of interventions against the detrimental effects of stress comes from complementary medicine. Complementary and Alternative Medicine (CAM) or complementary medicine has spread considerably over the last three decades. Compared to the popularity of the methods in the general population the available data regarding efficiency and efficacy of the methods is generally not strong. The german term “Erfahrungsmedizin” which can be translated to “experienced-based medicine” shows the self-identity of the methods. Priority has the experience of the individual and scientific principles are not focal. One of the widely-known methods in Switzerland is kinesiology and shall be depicted in detail.

4.3.1 Overview complementary and alternative medicine

4.3.1.1 Definition of complementary medicine

In the western world, there has been a movement in the field of health care. It will be shown that the rates of utilization of complementary medicine have risen and that it may be assumed that in the US and Europe there are hardly any people that do not have at least a very vague idea of what complementary medicine is (Köntopp, 2004). Acupuncture or homeopathy are terms that almost belong to the general vocabulary. But the field of complementary medicine is widespread and there are many, oftentimes quasi-analogous, terms to describe those methods outside of conventional medicine. The naming of the field itself is part of an ongoing discussion. Before the 1970s many other terms had been in use, f.e. “biological medicine”, “holistic medicine” or “experience-based medicine” as well as “natural medicine” (Uehleke & Saller, 2011). Over the last three decades there have been numerous efforts to define complementary medicine, but there is lack of consensus about definitions even though this may have negative implications for research and clinical practice (Falkenberg et al., 2012). Academically the term CAM is widespread and the two parts complementary and alternative are often used as synonyms and differences in understanding of these terms are often marginal (Caspi et al., 2003). The definition that “the sum of unconventional therapies is CAM” is not selective enough and too fuzzy (Uehleke & Saller, 2011). Interestingly to date there is a European as well as an American definition of what CAM is. The European CAMbrella project defined CAM as follows: “CAM utilized by European citizens represents a variety of different medical systems and therapies based on the knowledge, skills and practices derived from theories, philosophies and experiences used to maintain and improve health, as well as to prevent, diagnose, relieve or treat physical and mental illnesses. CAM has been mainly used outside conventional health care, but in some countries certain treatments are being adopted or adapted by conventional health care (Eardley et al., 2012).” The National center for Complementary and Integrative Health (NCCIH), part of the National Institutes of Health (NIH), defines CAM as group of different interventions that belong not yet to conventional medicine. A unifying characteristic is that mostly there is not yet enough evidence that they are accepted as part of conventional medicine (NCCIH, 2014). This US definition divides

CAM into five main domains: Alternative medicine systems, biologically based practices, manipulative and body-based therapies, mind-body interventions, and energy therapies (NCCIH, 2014).

4.3.1.2 Usage of complementary medicine

The usage of methods of complementary medicine is widespread in the population of Europe, the United States and Australia. The World Health Organization (WHO) published the WHO Traditional Medicine Strategy 2014-2023, which recognized that the demand for complementary medicine is increasing globally (WHO, 2014). Nearly 40% of American adults have used one or more therapies that fall into one of the five domains of complementary medicine (Clarke et al., 2015) and this is underlined by the findings of a research project by Versnik Nowak et al. (2015) who found that nearly 80% of Ivy league college students had used at least one form of complementary medicine in the last 12 months. For Europe prevalence data has been shown to be between 0.3 – 86%. The data showed substantial heterogeneity and the picture of complementary medicine prevalence across the EU member states remains unclear (Eardley et al., 2012). However, the European Information Centre of Complementary & Alternative Medicine (EICCAM, 2008) suggest that more than 100 million EU citizens are regular users of CAM. In Switzerland, the following situation presents itself regarding CAM: With a remarkable 2/3 of the Swiss population voting in a national referendum in favor of complementary medicine being anchored in the federal constitution this was interpreted as unambiguous to include complementary medicine as part of modern medicine (Saller, 2009). Klein et al. (2015) found, that 25% of Swiss of 15 and older had used at least one method of complementary medicine in the previous 12 months and in a longitudinal study in Switzerland Rössler et al. (2007) found an increase of usage of complementary medicine of 34.7% from 1993 (21.9%) to 1999 (29.5%). Also, the significance of complementary medicine may be derived from the fact that 59.9% of the adult population had a supplemental health insurance that partly covered such treatments (Klein et al., 2015).

Table 8: Five major types domains of CAM (NCCIH, 2014)

	Description	Examples of methods
Whole Medical Systems	Whole medical systems are built upon complete systems of theory and practice. These systems have evolved apart from and earlier than the conventional medical approach.	• Traditional Chinese Medicine • Ayurveda • Homeopathy
Biologically based Practices	They use substances found in nature, such as herbs, foods, and vitamins.	• Dietary supplements • Herbal products • Phytotherapy
Manipulative and body-based Therapies	Therapies that are based on manipulation and/or movement of one or more parts of the body.	• Massage • Chiropractic • Osteopathy
Mind-Body interventions	These interventions use a variety of techniques designed to enhance the mind's capacity to affect bodily functions and symptoms. Some techniques that were considered CAM in the past have become mainstream (f.e. patient support groups and cognitive-behavioral therapy)	• Meditation • Therapies that use creative outlets such as art, music, or dance • Kinesiology
Energy therapies	Energy therapies involve the use of energy fields: *Biofield therapies:* are intended to affect energy fields that purportedly surround and penetrate the human body. *Bioelectromagnetic-based therapies:* Involve the unconventional use of electromagnetic fields	*Biofield therapies:* • Qi Gong • Therapeutic touch *Bioelectromagnetic-based therapies:* • Pulsed fields • Magnetic fields

4.3.2 Development of Kinesiology and Integrative Kinesiology

Kinesiology was initially developed by the Chiropractor George Goodheart in the 1960s. Goodheart started experimenting with a biofeedback system that was first used in physiotherapy and later in chiropractic and which is known as manual muscle testing (MMT). He

observed that sometimes a muscle tested weak, but there was no atrophy or other apparent reason for the weakness. On one occasion he observed nodules at the origin of the patient's serratus anterior muscle and upon deep goading of the nodules, the muscle immediately returned to almost normal strength (Walther, 2000). This experience led to discovery of Applied Kinesiology and the initial development toward correcting structural imbalance caused by poorly functioning muscles. Goodheart came up with a new idea for working with muscles. He concluded that when muscles felt tight, or in spasm, causing pain and pulling the spine out of line it was not really the symptomatic muscle causing the trouble, but that weak muscles on one side of the body can cause normal muscles opposing to become or seem tight. The general idea was rather than working with the symptomatic muscle, the weak muscle should be strengthened (Thie, 1973). The MMT became the instrument of AK to understand the "body language" and to use the muscles as indicators. The technique of muscle testing Goodheart used was that of physiotherapists Florence and Henry Kendall (Goodheart, 2000). Consequently, the method was termed Applied Kinesiology (AK) and the word kinesiology indicates that AK essentially is about movement, specifically about activation and movement of muscles.

4.3.3 Philosophy and Principles of Kinesiology

The philosophical background of kinesiology is an assumption shared with chiropractic. It is that the body has an "innate intelligence", the ability of the body to regulate and repair itself, which is also referred to as homeostasis. Therefore, it is the endeavor of the therapist to strengthen the body for that it can heal itself. The assumption can be summarized to: Health comes from within. The founder of chiropractic, Daniel D. Palmer, postulated another important element of kinesiology which is the idea of the "Triad of Health" (Palmer, 1911). It is a holistic model where health is composed of structural, chemical and mental factors that should be balanced, forming an equilateral triangle. When a person experiences symptoms or poor health one or more of the three factors are out of balance (Walther, 2000). Kinesiology may then be used to identify the triad's balance and with which interventions the equilibrium may be reinstated. The innate intelligence that governs the whole system may be seen as a self-regulating system.

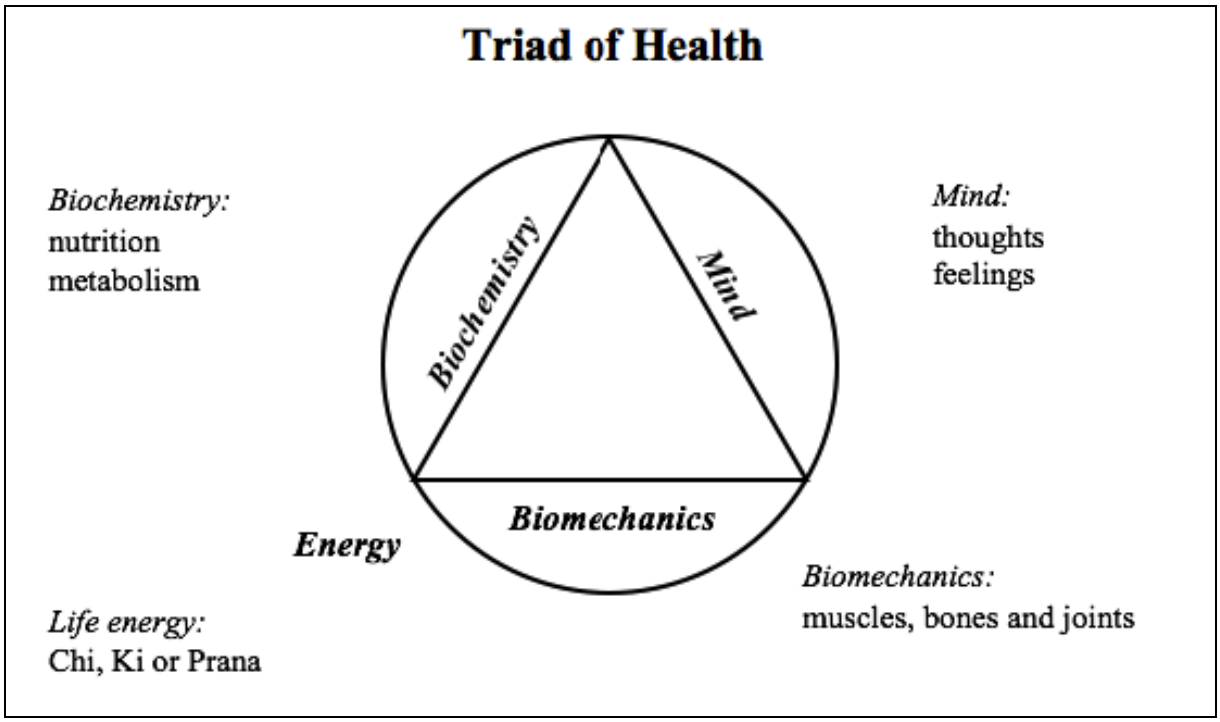

Figure 8: Triad of Health

This view is complemented by theoretical aspects of ancient and Traditional Chinese Medicine (TCM). Biochemistry, anatomy, and physiology form the groundwork for modern biomedicine, but are of little importance to traditional East Asian medicine. What it concerns is organizing signs and symptoms to arrive at an accurate perception of "what is going on" (Kaptchuk, 2000). Chinese medicine looks at the patient and is not seeking a pathological mechanism behind the veil of symptoms. What concerns the medical professional in Chinese medicine, is gaining a flexible perspective on the dynamic texture of a person's life. The first goal, right after the therapeutic alliance, is to organize signs and symptoms to an emblematic image. Fundamental are the ideas of life energy Chi, the polar principles of Yin and Yang as well as the theory of the Five Elements. Especially important is the notion of Chi in TCM medical thought. While Chi sometimes is translated to "vital energy", it is much more than that. As Chinese thoughts distinguish less between matter and energy, Chi is in between. But it is also the thread connecting all being and may take a myriad of forms (Kaptchuk, 2000). It could be hypothesized that "innate intelligence" is only a form of Chi and that kinesiology is about bringing Chi into balance in the human being.

4.3.4 Procedures and techniques

The integration of Chinese medicine and philosophy into kinesiology made it possible to see physical, mental/emotional and chemical dysbalances as expressions of energetic patterns. Therefore, the kinesiological perspective is the combination of the holistic western (Triad of health) and the holistic eastern (Chi) health models. The results of the MMT indicate a dysbalanced of Chi and which intervention is able to harmonize it. The MMT is the tool which enables a biofeedback that adds to the perception and communication in the therapeutic setting. The MMT promotes self-awareness by indicating to dysbalances, before they are cognitively accessible. The work in clinical practice suggests that in kinesiology forms such as Integrative Kinesiology (IK), the therapeutic dialogue with integration of the MMT leads to situations where cognitive aspects of a problem are complemented by aspects that are subconsciously stored. This integration of conscious and subconscious in relation to the problem situation, helps to gather relevant information as to what is helpful and what are harmful behaviors and attitudes. This leads to a more differentiated self-perception and to resources that may be utilized for the healing process. Those resources may than be supported by activating meridians, different reflex points or other kinesiological balancing techniques.

4.3.5 Different forms of Kinesiology

AK and its discoveries were the pillar on which various forms of kinesiology developed. Fundamentally there are two forms of kinesiology that need to be distinguished: a) Applied Kinesiology and b) Specialized Kinesiology.

Table 9: Forms of kinesiology

	Applied Kinesiology	**Specialized Kinesiology**
Who can learn it	Limited to medical professionals such as: • Chiropractors • Osteopathists • Physiotherapists • Registered Naturopaths	Open to non-medical applicants

Muscle test result	• MMT as diagnostic tool in conjunction with other diagnostic tools utilized • Momentarily and situational dependent result of the MMT .	• Indicating energetic dysbalance (energetic diagnose) • Momentarily and situational dependent result of the MMT
Clients	• Patients for and within medical care • Healthy individuals (less frequent)	• Healthy individuals (frequent) • Complementary treatment with patients in medical care
Commercial name(s)	• Applied Kinesiology (AK)	• Kinesiologie or in german also "Angewandte Kinesiologie» • Edu-Kinesthetics / Brain Gym • Integrative Kinesiology (IK) • Wellness-Kinesiology and many other

Even in peer reviewed journals there is a lack of distinction between these two classes of kinesiology found. Eardley et al. (2013) report of Professional Kinesiology Practice (PKP), a form of specialized kinesiology, but then write about the "diagnostic tool the muscle test" is being used where at best it could be an energetic diagnose, and by definition not a diagnose in the sense of medical diagnose.

In the 1970s John Thie developed the first non-diagnostic form of kinesiology and for reasons of clarity it was named "Touch for Health" and specifically not kinesiology. Thie included easy to use techniques from AK that did not have any contraindications and built a solution-oriented, salutgenetic form of kinesiology. Touch for Health's goal was to be effective in the health prevention and help families to proactively and self-competent promote their health (Thie, 1973). While the MMT was used it was only to identify where the energy Chi is not in balance and to restore it with body-oriented balance techniques such as massage of reflex points or meridian activation. The MMT was strictly used to indicate dysbalances and identify the resource that could restore it. Success of the intervention was evaluated on a visual or verbal analogue scale. On the basis of Touch for Health a second generation of kinesiology methods developed. Those include for example:

Table 10: Second generation of kinesiology types

Name of kinesiology	Founder	Length of training
Applied Physiology (Utt, 1997)	Richard Utt	Weekend / Weekly seminars
Edu-Kinesthetic (Dennison, 2006)	Paul Dennison	Weekend / Weekly seminars
Hyperton X (Mahony, 1993)	Frank Mahony	Weekend / Weekly seminars
Integrative Kinesiology (Sonderegger, 2005)	Rosmarie Sonderegger	3 years professional program
Professional Kinesiology Practitioner (Dewe, 1990)	Bruce Dewe 1942 –	Weekend / Weekly seminars
Three in one Concepts (Stokes & Whiteside, 2007)	Gordon Stokes and Daniel Whiteside	Weekend / Weekly seminars

These types of kinesiology vary mainly in the interpretation of the MMT, the techniques applied and the form of client/therapist interaction. Tschernitschek and Fink (2005) in their review suggest that there is need for clear definitions of the groups of kinesiology. The field of Specialized Kinesiology may be divided in sectors as well:

Table 11: Dialogue interaction with therapist – underlying assumptions accepted by conventional medicine

		High	**Low**
		Importance of dialogue with therapist	**Importance of dialogue with therapist**
High	**Underlying assumptions (other than kinesiological) are currently accepted by conventional medicine**	IK Edu-K	TFH
Low	**Underlying assumptions are currently accepted by conventional medicine**		3 in 1 Applied Phyisology Hyperton-X

The client experience and satisfaction has to our knowledge not been researched. With the heterogeneity of types of kinesiology it could be expected, that orientation in the field of kinesiology and deciding what or what not to choose is experienced as difficult by clients interested to choose the method.

In Switzerland, the significance of complementary medicine may be derived from the fact that Klein et al. (2015) have shown that 59.9% of the adult population had a supplemental health insurance that covered complementary medicine treatments and consequently also kinesiology. To our knowledge there is not much recent data regarding the utilization of kinesiology for health reasons or how many therapists are active with kinesiology. In 1998 Kristof et al. found that 31% of the Swiss women they surveyed had experienced kinesiology, but the sample was relatively small and further research would be helpful. The recent development of professional development of complementary medicine has led to an advanced federal diploma of professional education and training in complementary therapy in which kinesiology is included as a method (OdA KT, 2012). The profile of profession as well as the structured process of accrediting professional programs is expected to lead to better treatment results and is part of the development from a simple complementary methods to a veritable profession.

4.3.6 Limitations and ethical considerations of Kinesiology

The MMT is easy to perform, but complex to interpret. At first sight the results of the MMT might reflect a yes/no-scheme with the result being some kind of truth-finder. While for lay people this interpretation might be standing to reason, it is a simplification that does not reflect the complexity of the process and is not vindicable (Sonderegger, 2008). Already Goodheart emphasized that the MMT indicates more pre-clinical conditions and is for AK a supplement to the existing medical diagnostic instruments (Schmitt & Cuthbert, 2008). The following considerations are important: The MMT result is a momentarily reflection of the energy system taken in a working context between a therapist and a client. Solitary the MMT is not valid to base decisions on the results or make any (medical) diagnosis with it. It is only with the contextual interpretation of the result that it becomes a valid instrument of communication and indication of inner processes. The results need to put into perspective of the clients

life experience and a coherent fit in for the client. A kinesiological intervention therefore always needs to be reflected upon the context it developed and development steps should promote the dynamic personal equilibrium (Sonderegger, 2005; Sonderegger, 2008).

4.3.7 Integrative Kinesiology

In the early 1980s Rosmarie Sonderegger a licensed social worker and psychologist got into contact with TFH in Switzerland. With her person-centered psychological education, she worked in a private practice with clients. Upon learning the MMT and TFH from John Thie personally she immediately integrated the techniques in her private sessions work with clients. She used the MMT during the conversation with the client to make subconscious dysfunctional patterns conscious and cognitively accessible. She noticed that the clients were able to reflect and alter behavior and thought patterns faster and that the effect sustained. Clients felt positive and better after the sessions and seemed to reach their therapy goal earlier (Sonderegger, 2005). It may be hypothesized that through the person-centered dialog in combination with the MMT the clients would gain a deeper self-understanding and the question was if the MMT acted as a form of indicator system of automatic thoughts and emotions. This type of kinesiology was termed integrative because it integrated therapeutic conversation into a formerly body-technique only.

4.3.8 Therapeutic approach of Integrative Kinesiology

The method is being used in one on one setting as well as in group settings. In the therapeutic setting with client and kinesiologist the process begins with a systematic review of the clients' concern. In this *encounter phase* the emphasis is on building rapport, understanding the issue and what the favorable direction of development is. The second phase, termed *process phase*, the MMT is used as biofeedback instrument to challenge assumptions, discover areas of strain and what the underlying inhibiting process could be. It is being ascertained what cognitive respectively emotional patterns or what physical inhibitions might be connected to the topic and how they may be transformed with kinesiological interventions. The *integration phase*

then activates the bodily system with congenial kinesiological techniques aimed at activating the bodily resources. The kinesiological process is completed with the *transformation phase* in which it is being elaborated on how to support the process in the time to follow. The group setting also follows the four process steps, with the difference that a topic is presented at the beginning and then processed with the group.

4.3.9 Evaluation of kinesiology

The evaluation of kinesiology may be attempted by trying to identify the fundamental principles behind the method or trying to capture the effects of the intervention. The former would be what Heinz von Foerster called the way of "scientia", the word which stems from the indoeuropean "ski" which is in sci-ence ord schi-zophrenia and is the word for separation (Mikulás & Moser, 2013). The idea behind it is to understand the whole, it needs to be separated in its parts and those must be understood first. The question may be raised if a treatment approach with a holistic philosophical approach would not better be researched as a system and therefore, would prioritize the evaluation of efficacy and efficiency and in a second phase the underlying principles.

AK as well as kinesiology fields have been subject to various research projects (f.e. Eardley et al., 2013; Schwartz et al., 2014) as well as to review articles (f.e. Cuthbert & Goodheart, 2007; Hall et al., 2008; Rosner & Cuthbert, 2012 or Tschernitscheck & Fink, 2005). The evidence found is ambivalent. There are several issues but quality of research projects in many cases does not fulfill the requirements of scientific standards (Hall et al., 2008; Jensen et al., 2016). A common problem that confounds the research is the differentiation of the types of kinesiology, especially between the diagnostic form of AK and the holistic form of specialized kinesiologies. In research projects (f.e. Jensen et al., 2016) the MMT is used as a standalone diagnostic test which is against the theoretical principles of the MMT. Jensen et al. (2016) as well as Tschernitschek urge the field of kinesiology to conduct randomized controlled trials (RCT) with standards that are accepted by the scientific community.

However, as the field of complementary medicine and therefore also kinesiology is less popular in traditional medicine, the scientific approach to evaluate interventions is less known. It is therefore important to define research protocols that are easy to apply and are cost effective. Also it should be based on a research protocol that has been extensively published in order to ensure that it is widely accepted. To further gain understanding of complementary methods and aid future research has been an important part of formulating this research project.

PART II: EMPIRICAL STUDY

5 Summary and research question

Maintaining health in a complex and globalized world with almost unlimited daily and chronic challenges is important, both from a therapeutical microperspective as well as from a societal macroperspective. This view may have contributed to the Swiss Federal Council's decision to define in its "Health 2020" strategy that an effective system of mental health prevention should be developed and that the focal point should be on the individual to raise the health competence and improve well-being (Swiss Federal Department of Home Affairs, 2013). In congruence with this mission and with the idea to not only evaluate a two day group stress management seminar, we went forward to compare a known method of complementary medicine within this study. The rational behind this was a) that complementary medicine is a growing field that has not been subject to many RCT research projects, but also b) test a study design that could be used for various methods that claim to help reducing stress. In review articles by Hall et al. (2008) as well as Tschernitschek and Fink (2005) pragmatic studies on the effectiveness of kinesiology were demanded as they did not find sufficient studies that used adequate protocols to assess the effectiveness of the method.

Hence, we hypothesized that

a) The stress management group will show blunted cortisol responses in a standardized psychosocial stress test compared to the control group

b) The kinesiology group will show blunted cortisol responses in a standardized psychosocial stress test compared to the control group

c) Both treatment groups will show favourable development in the psychometric characteristics measured at the beginning of the study and again before the day of the psychosocial stress test.

Therefore, the primary purpose of this thesis was to evaluate the effects of kinesiology and cognitive behavioral stress management on psychological well-being as well as on neuroendocrine response to a standardized stress test in healthy participants. A secondary goal was to review and promote a test procedure, which could be utilized for intervention studies in further methods of complementary medicine.

6 The IKSIT study

The study was conducted in Zurich (Switzerland) over a period of six months. It followed a detailed plan that is depicted in the following:

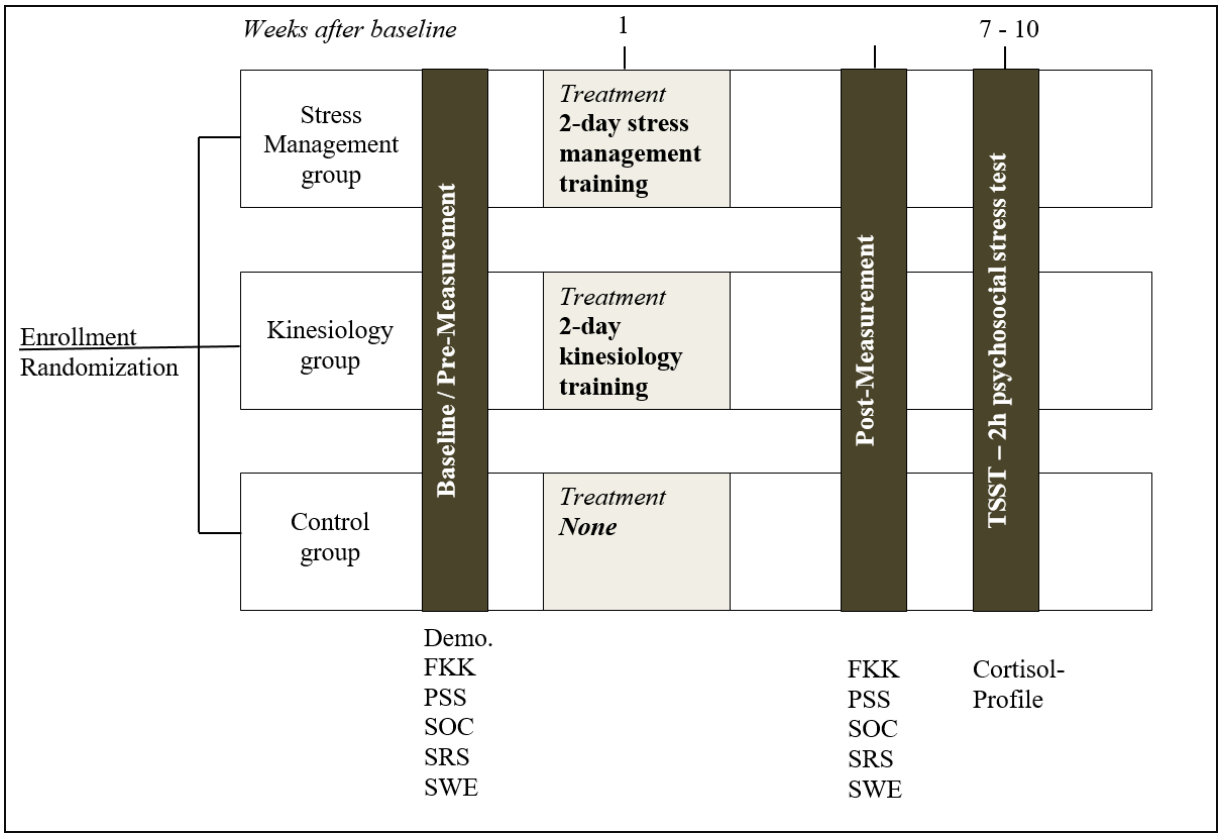

Figure 11: Outline of the research project. FKK (Selfconcept of own competence); PSS (Perceived Stress Scale); SOC (Sense of Coherence); SRS (Stress Reactivity Scale), SWE (Perceived Self-Efficacy)

6.1 Methods

6.1.1 Participants

Before the recruitment process was initiated the research protocol was submitted to the ethics committee of the Canton of Zurich, Switzerland and registered at ClinicalTrials.gov (ClinicalTrials.gov number, CT01331577). The ethics committee decided that the study was harmless and formal approval of the ethics committee not necessary. The study was conducted according to the declaration of Helsinki. Advertisement of the study was via online publication and a website in which the study as well as the exclusion criteria were briefly described. Interested healthy subjects had the opportunity to enroll online. The subjects had to be between 18 and 50 years of age, accepted randomization and were fluent in German. They were then sent a screening questionnaire, containing exclusion criteria designed to reduce confounding factors that have shown to affect physiological dependent measures: Any previous participation in stress research projects (to ensure novelty to the TSST protocol), regular or occasional intake of any medication or addictive substances, any self-reported acute or chronic somatic or mental disorders, smoking more than five cigarettes/day, consumption of more than 2 alcoholic drinks/day or any previous practical experience with stress management training or kinesiology. If women were pregnant, were planning a pregnancy or were using oral contraceptives during the study they were also excluded. This information was confirmed in a telephone interview in which all subjects received an oral description of the study and were able to clarify questions. Subsequently, the subjects were also provided with a complete written description of the study and written informed consent was obtained. Once baseline examination was completed, the participants were randomly assigned to either the

stress management group (SMG), kinesiology group (KIG) or the waiting list control group (CG). An independent research assistant performed the structured randomization procedure. Allocation concealment was achieved through the use of sequentially numbered, opaque and sealed envelopes. To assure gender balance the procedure was performed for women and men separately. The participant inclusion process is depicted in Figure 11.

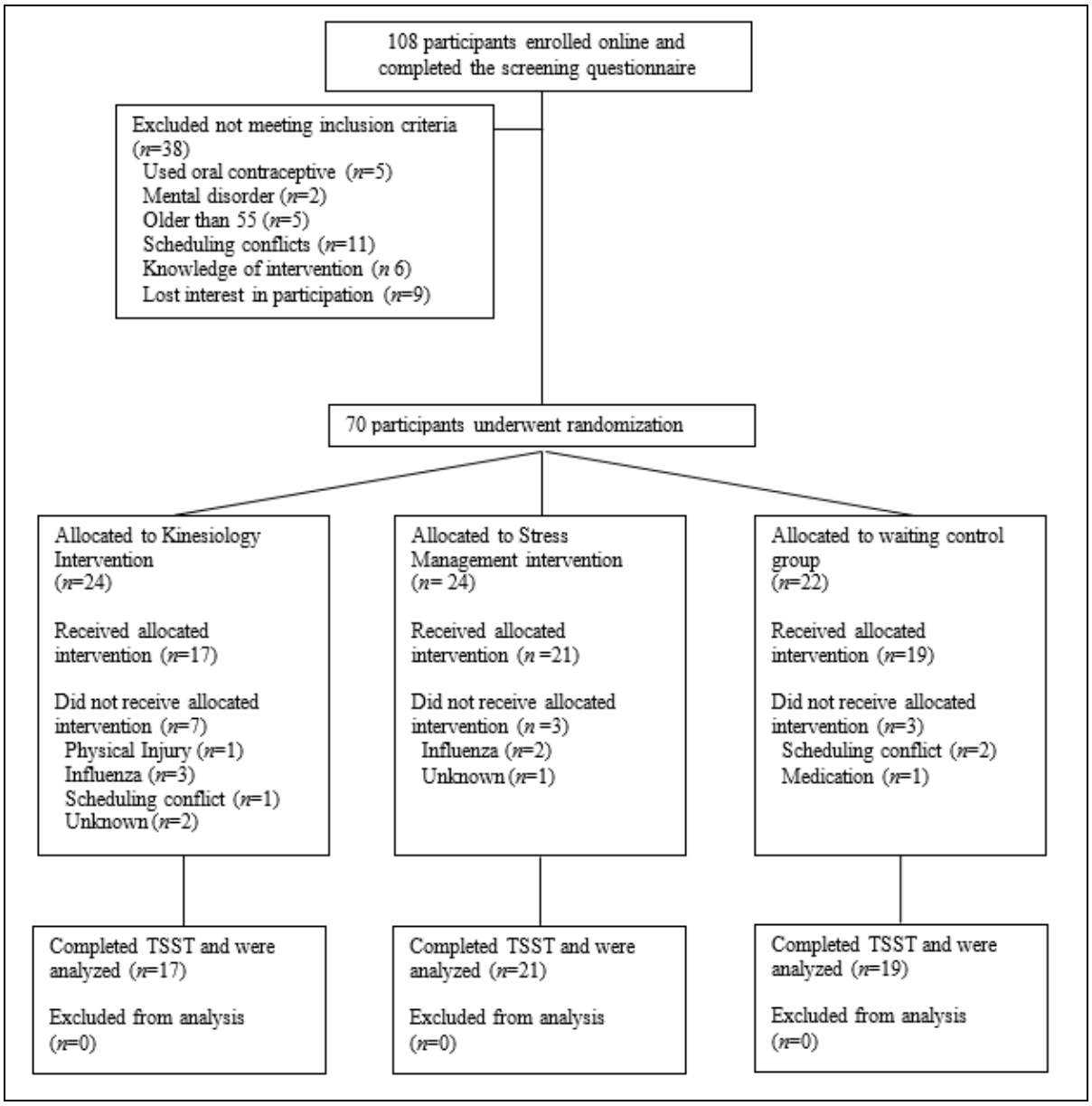

Figure 11: Flow diagram for the progress through the phases of the randomized trial (based on the consolidated standards of reporting trials (CONSORT) recommendations.

6.1.2 Procedure

Two different approaches for future coping with stress were applied to separate groups, while the CG absolved the training after completion of the study. After allotment to the group the participants were invited to a two-day group seminar (Saturday and Sunday). Daily sessions lasted from 9.00 a.m. to 5 p.m. and were performed by two experienced therapists in cognitive behavior therapy and kinesiology respectively. Both trainers had the same experience and were both female. Also both groups followed a standardized training manual. No exercises or role-plays used in the training resembled the situation used in the standardized stress test.

6.1.2.1 Stress management training

The SMG attended a group-based cognitive-behavioral stress management (CBSM) training which based on the principles of the stress inoculation training developed by Meichenbaum (1985) and is described in detail elsewhere (Gaab et al., 2003). During the two days the training focused on four cognitive-behavioral techniques: cognitive restructuring, problem solving, self-instruction as well as relaxation modules (progressive muscle relaxation). After a theoretical introduction and a group-discussion about the transactional stress concept, each stress-reducing technique was introduced and practiced. All participants received a training manual containing a summary of the applied theoretical models as well as the descriptions of the stress reducing techniques.

6.1.2.2 Kinesiology treatment

The second treatment group underwent kinesiology training. Kinesiology is a complementary health approach, which is categorized under the mind-body practices. The U.S. National Institutes of Health (2010) characterized these as methods focusing on the interactions among the brain, mind, body, and behavior, with the intent of using those interactions to promote health. Kinesiology as a term is used for a wide variety of methods utilizing subtle change in manual muscle testing to detect information about mind-body processes. It is based on the concept of balanced qi (an ancient term given to what is believed to be vital energy) that is assumed to flow through meridians throughout the body. Qi is proposed to regulate a persons' emotional, mental and physical balance. To the contrary disease is seen as a consequence of an imbalance of qi. The belief is that all of the body's systems work together and that disturbances in the qi energy system may affect function elsewhere in the body. Kinesiology seeks to restore the mind/body balance by utilizing different techniques. Among the components are goal-setting, acupressure, massage, meridian activation and exercises. However, kinesiology needs to be differentiated into the medical and diagnostic form of kinesiology called Applied Kinesiology and non-medical, non-diagnostic forms of kinesiology, which are described elsewhere (McDowall & Cuthbert, 2008; Sonderegger, 2008). During the two days the kinesiology training focused on the following content: Introduction to the concept of kinesiology and stress, muscle testing and applying it to discover personal areas of stress, kinesiology exercises, acupressure tapping technique as well as goal setting in challenging situations to reduce negative effects of stress. All participants received a training manual containing a summary of the workshop as well as the descriptions of the stress reducing techniques.

6.1.2.3 Psychosocial Stress Test

The Trier Social Stress Test (TSST) is a laboratory protocol for reliable stimulation of biomarkers of psychosocial stress (Dickerson & Kemeny, 2004). It has repeatedly been found to induce profound endocrine responses in 70-85% of the participants tested (Kirschbaum et al., 1993; Foley & Kirschbaum, 2010). Participants were invited to a scheduled appointment between 2 p.m. and 6 p.m. in a building and setting novel to all participants. With the invitation participants had been instructed not to eat, drink anything but water 2 hours preceding the TSST and to refrain from intense physical activities 24h before the experiment. All personnel involved during the experiment were blind to group assignment. Upon arrival they were welcomed and received a high glucose drink (300ml) to raise blood glucose levels, as low glucose levels have been shown by Kirschbaum et al. (1997) to blunt stress-induced increases of cortisol. After a brief introduction to the TSST (2 minutes) they gave a basal sample of salivary free cortisol. In a separate preparation room, they had 10 minutes alone to prepare for an imaginary job interview and they then performed the mock job interview (5 minutes) as well as the mental arithmetic exercise (5 minutes) 2 m in front of two evaluative panel members dressed in white laboratory coats and a video camera (Kirschbaum et al., 1993). The panel consisted of one female and one male member (female psychologist and male retired manager). Saliva samples were obtained immediately before, and one, 10, 20, 30, 45 and 60 min after the TSST. After completion all participants were debriefed and asked to refrain from informing other participants regarding the TSST.

6.1.3 Outcome measures

For the evaluation of training effects psychometric as well as physiological measures were obtained. Stress reactivity of repeated salivary cortisol levels (i.e. the interaction group-by-stress) was defined as the primary outcome measure. Secondary measures were development of the psychometric assessments over the period of the study. Points of measurement were:

1. After randomization but before group-treatment, respectively waiting condition. All participants were given a set of questionnaires to allow assessment of the development of psychological characteristics during the course of the study. The questionnaires (see below) were administered at baseline and after the group intervention, one week prior to the TSST examination day.

2. For the endocrine evaluation of stress salivary free cortisol was chosen as biomarker. The collection of saliva is non-invasive, the procedure straightforward and due to the numerous publications using it as measure for the hypothalamus—pituitary—adrenal axis´ (HPAA) adaptation to stress it was seen as very well evaluated and well-established. Therefore, at the examination day stress reactivity was measured through the cortisol profile during TSST procedure.

6.1.3.1 Psychometric measures

The psychological development in the domains of depressive symptoms (ADS-K), perceived stress (PSS) and stress reactivity (SRS), sense of coherence (SOC), self-concept (FKK) as

well as self-efficacy (SWE) during the test period were measured with the following psychometric instruments:

Center for Epidemiological Studies Depression Scale (Radloff, 1977), German version (Allgemeine Depressions Skala-Kurzform (ADS-K), Hautzinger & Bailer, 1993). It was specifically developed to assess depressive affect and negative thought patterns for use in investigations in nonclinical samples. It has shown good internal consistency with Cronbach's $\alpha = .90$.

Questionnaire for Competence and Control Orientations (Fragebogen zur Kontrollüberzeugung und Kompetenzerwartung (FKK)). The 32-item questionnaire (Krampen, 1989) assesses the following personality traits (Cronbach's α): self-concept of own competence (Cronbach's $\alpha = .76$), chance control (Cronbach's $\alpha = .75$), internality (Cronbach's $\alpha = .70$) and powerful others control (Cronbach's $\alpha = .73$).

Perceived Stress Scale (PSS). This 10-item questionnaire (Cronbach's $\alpha = .78$) was used to assess the degree to which situations in life (in the last month) were perceived as stressful. Items were designed to assess how predictable, uncontrollable, and overloading participants perceive their lives (Cohen & Williamson, 1988).

Sense of Coherence (SOC). SOC is an important resource promoting coping and health in daily life stressful events (Eriksson & Lindström, 2005). It is characterized as a personal way of thinking, being, and acting, with an inner trust, which leads people to identify, benefit, use

and re-use the resources at their disposal (Lindstöm & Eriksson, 2005). The SOC-L9 (Schumacher et al., 2000) is conceptualized as a unidimensional scale assessing the sense of coherence in a reliable, valid and economical way (Cronbach's α = .87).

Stress Reactivity Scale (SRS). Stressreactivity is the extent to which people are likely to show emotional or physical reactions to stressful events. Schulz et al. (2005) recommend the questionnaire specifically as a tool to evaluate stress management programs. Good internal consistency is reported (Cronbach's α = .91).

Self Efficacy Scale (Selbstwirksamkeitserwartung, SWE). The scale assesses a general sense of perceived self-efficacy with the aim to predict coping with daily hassles as well as adaptation after experiencing stressful life events. Schwarzer and Jerusalem (1995) report good internal consistency (Cronbach's α = between .80 and .90)

6.1.3.2 Endocrinological measurement

Saliva was collected using Salivette (Sarstedt AG, Sevelen, Switzerland) collection devices. Samples were stored at -20°C until biochemical analysis took place. Salivary free cortisol was analyzed by using a commercial chemiluminescence immunoassay with high sensitivity of 0.16 ng/ml (IBL Hamburg, Germany). Inter- and intra-assay coefficients of variation were below 10%. To reduce error variance caused by imprecision of the intra-assay all samples

were analyzed in the same run in our biochemical laboratory of the Institute of Psychology at the University of Zurich.

6.1.4 Statistical Analysis

Data were analyzed using SPSS (Version 19) statistical software package for Macintosh (IBM SPSS Statistics. Somers, NY, USA). The optimal sample size of 64 has been calculated a priori using the statistical software G*Power (Faul et al., 2007). Prior stress management research with cortisol stress responses reported effect sizes ranging from $f^2 = .28 - .35$ (Gaab et al., 2003, Storch et al., 2007). The sample size was calculated to detect an expected medium to large effect size of $f^2 = .25$ with a power $\geq .85$ and $\alpha = .05$. Analyses of covariance and variance for repeated measures were computed to analyze endocrine responses between groups, controlling for differences in endocrine baseline levels when indicated. All reported results were corrected by the Greenhouse-Geisser procedure where appropriate (violation of sphericity assumption). Data were tested for normal distribution and homogeneity of variance using the Kolmogorov-Smirnov test and Levene's test before statistical procedures were applied. For all analyses, the significance level was $\alpha = 5\%$. Unless indicated, all results are shown as means and standard deviations.

6.2 Results

A total of 108 participants enrolled online on a website to participate in the study and completed the screening questionnaire. Reasons for exclusion were: use of oral contraceptive (*n*=5), mental disorder (*n*=2), over age of 55 (*n*=5), scheduling conflicts (*n*=11), knowledge of interevention (*n*=6). A total of nine participants lost interest in participation before they were

randomly assigned to one of the groups. The remaining 70 subjects (*N*=70) were randomly assigned either to the SMG (*n*=24), or KIG (*n*=24) or CG (*n*=22), which received intervention after participating in the TSST (Kirschbaum et al., 1993).

6.2.1 Descriptive group characteristics

Group characteristics collected and analyzed were age in years, gender, body mass index, education, sports activities hours per week and smoking habits (light smoking was defined as 5 cigarettes or less per day). The groups did not differ significantly in any of the descriptive characteristics (Table 10).

Table 10: Demographic, group-related, and psychometric group characteristics of the 57 subjects under study who completed pre- and post-measurements and the Trier Social Stress Test (TSST)

Characteristics	*KIG (n = 17)*	*SMG (n = 21)*	*CG (n = 19)*	*P*
Age[a] (years)	*36.29 (10.58)*	*33.48 (10.71)*	*31.74 (10.67)*	*.44*
Gender (male/female)	*3 / 14*	*7 / 14*	*5 / 14*	*.55*
Body Mass Index[a]	*22.20 (3.24)*	*23.28 (3.61)*	*22.68 (4.22)*	*.69*
Height[a] (cm)	*167.88 (7.82)*	*174.33 (9.11)*	*168.58 (10.03)*	*.06*
Weight[a] (kg)	*62.47 (9.12)*	*71.38 (15.43)*	*64.42 (12.97)*	*.09*
Education (with / without high school degree[b])	*15 / 2*	*16 / 5*	*16 / 3*	*.12*
Sports Activities[a] (hours / week)	*1.29 (.92)*	*1.24 (.77)*	*.84 (.76)*	*.19*
Smoking Habits (non smokers / light smokers[c])	*13 / 4*	*17 / 4*	*16 / 3*	*.65*

a Continuous data are expressed as mean ± SEM
b e.g. Swiss «Matura»
c Smoking less than 5 cigarettes per day.

6.2.2 Psychometric group characteristics

While the groups did not differ in the descriptive characteristics, we found significant differences in the pretreatment comparions of the psychometric characteristics of the groups. The depression scale ADS-K was significantly higher in the KIG (*M*=12.82, *SD*=5.73) compared to the SMG (*M*=7.81, *SD*=5.84) and CG group (*M*=11.68, *SD*=6.42) (ANOVA: $F(2,56) = 4.53$, p=0.01, eta^2=0.14).

Table 11. Psychometric characteristics of all participants at baseline

Questionnaires	*KIG (n = 17)*	*SMG (n = 21)*	*CG (n = 19)*	*Statistics*
ADS-K Depression	*12.82 (5.73)*	*7.81 (5.84)*	*11.68 (6.42)*	*$F(2,56) = 4.53$, $p = .01$, $eta^2 = .14$*
STAI-t Anxiety	*48.12 (1.87)*	*48.09 (3.16)*	*48.89 (2.90)*	*$F(2,56) = .52$, $p = .59$, $eta^2 = .02$*
FKK Competence and Control orientation				
Self-concept of own competence	*31.29 (8.02)*	*35.09 (6.41)*	*33.10 (4.23)*	*$F(2,56) = 1.70$, $p = .19$, $eta^2 = .06$*
PSS Perceived Stress Scale	*27.88 (5.79)*	*23.67 (5.94)*	*25.47 (6.83)*	*$F(2,56) = 2.17$, $p = .12$, $eta^2 = .07$*
SOC Sense of Coherence	*44.00 (9.10)*	*49.81 (8.56)*	*46.47 (6.54)*	*$F(2,56) = 2.46$, $p = .09$, $eta^2 = .08$*
SRS Stress Reactivity Scale, overall	*9.94 (2.92)*	*9.14 (2.39)*	*9.47 (2.09)*	*$F(2,56) = .49$, $p = .61$, $eta^2 = .02$*
SWE Perceived Self-Efficacy	*29.82 (4.00)*	*31.57 (4.76)*	*29.63 (3.37)*	*$F(2,56) = 1.35$, $p = .27$, $eta^2 = .05$*

Although not significant, but worth noting was that in 89.5% of all questionnaires the KIG exhibited health parameters that may be interpreted as inferior to the SMG and CG at base-line. In 10.5% this was the case for the CG, while the SMG always presented the most favorable means (Table 12).

6.2.3 Primary and secondary outcomes

6.2.3.1 Endocrine stress response evaluation: Trier Social Stress Test (TSST)

The endocrine stress response in the TSST resulted in a significant salivary free cortisol response (time effect: F (1.61/41.74, $p < 0.001$). ANCOVA (ADS-K post as covariate) showed that groups did not differ significantly in their baseline cortisol levels (group effect: F (2/53) = 0.343, $p = .711$), nor in their salivary free cortisol stress response over time (group by time interaction effect: F (2/53) = .295; p=.746).

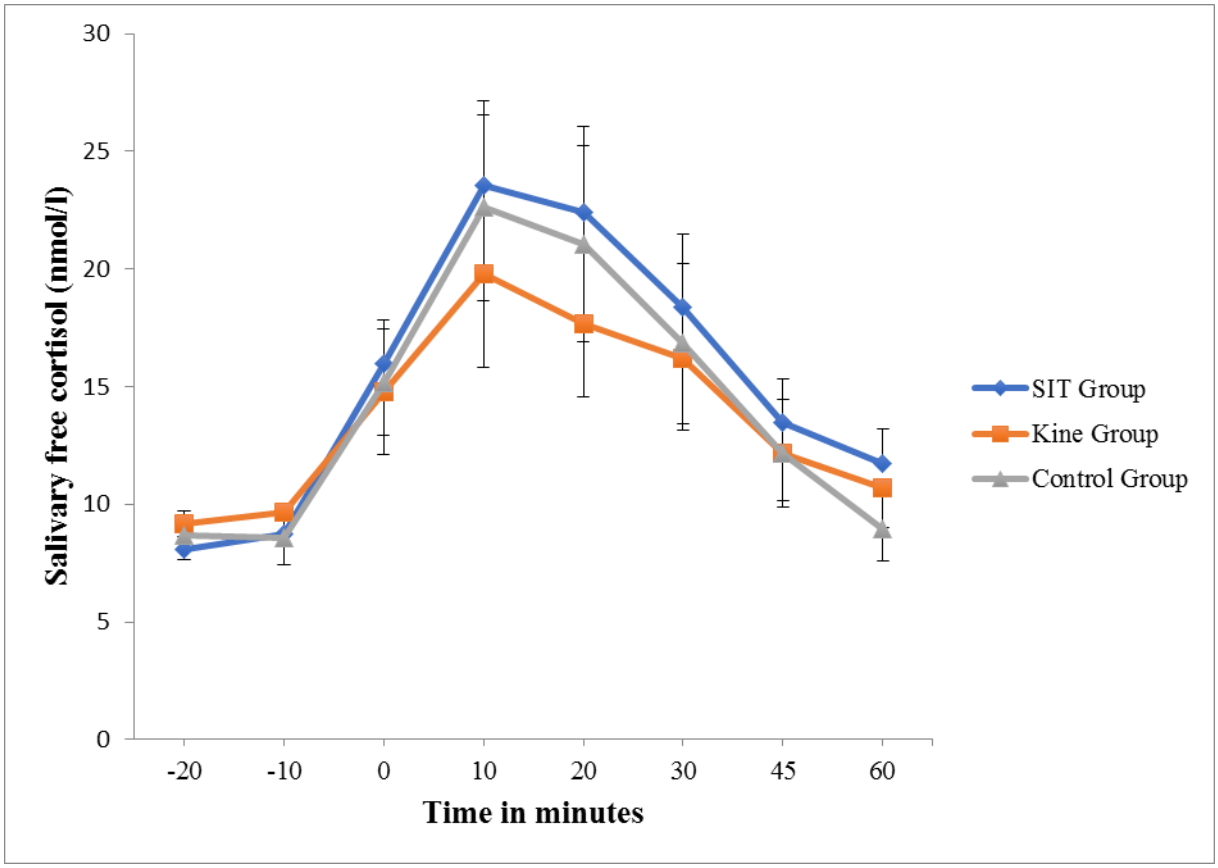

Figure 12: Cortisol development during TSST. Values are means ± S.E.M.

6.2.3.2 Psychometric evaluation of training effects: Changes from baseline

During the observation time, from pre- to post measurement, the groups did not differ regard the psychometric evaluation of the selfconcept of own competence, sense of coherence and perceived self-efficacy (Detailed in table 12).

6.2.3.3 Psychometric evaluation of training effects: Changes from baseline

With regard to measured aspects of depressive affect, anxiety, perceived stress or stress reactivity the groups did not differ significantly during the period of examination. Details are depicted in table 13.

Table 12. Pre/post comparison of the groups for selfconcept, sense of coherence and self-efficacy

Questionnaires	Kine Group (n = 17)	SIT Group (n = 21)	Control Group (n = 19)	Statistics
Selfconcept of own competence				
Selfconcept – pre	31.29 (8.02)	35.09 (6.41)	33.10 (4.23)	$F(2,56) = 1.70$, $p = .19$, $eta^2 = .06$
Selfconcept–post	30.70 (7.32)	36.52 (6.01)	32.47 (3.63)	$F(2,56) = 5.12$, $p = .01$, $eta^2 = .16$
Internality of general comp. belief – pre	32.59 (5.30)	34.09 (5.04)	32.68 (4.90)	$F(2,56) = .55$, $p = .58$, $eta^2 = .02$
Internality of general comp. belief – post	33.53 (5.49)	33.38 (4.74)	32.68 (3.57)	$F(2,56) = .18$, $p = .84$, $eta^2 = .01$
Selfefficacy – pre	63.88 (10.27)	69.19 (10.75)	65.79 (7.48)	$F(2,56) = 1.50$, $p = .23$, $eta^2 = .05$
Selfefficacy – post	64.23 (9.72)	69.90 (9.82)	65.16 (5.76)	$F(2,56) = 2.43$, $p = .09$, $eta^2 = .08$
Social ext. – pre	21.65 (4.78)	20.95 (5.66)	21.31 (4.84)	$F(2,56) = .09$, $p = .92$, $eta^2 = .00$
Social ext. - post	22.88 (5.34)	19.38 (6.64)	22.00 (5.32)	$F(2,56) = 1.89$, $p = .16$, $eta^2 = .06$
Fatalistic ext. - pre	23.82 (5.46)	22.00 (5.56)	23.74 (4.87)	$F(2,56) = .74$, $p = .48$, $eta^2 = .03$
Fatalistic ext. – post	25.12 (4.28)	21.33 (5.86)	23.63 (4.29)	$F(2,56) = 2.86$, $p = .06$, $eta^2 = .09$
Externality – pre	45.47 (9.12)	42.95 (9.99)	45.05 (8.56)	$F(2,56) = .42$, $p = .66$, $eta^2 = .01$
Externality – post	48.00 (8.01)	40.71 (11.70)	45.63 (8.49)	$F(2,56) = 2.84$, $p = .07$, $eta^2 = .09$
Gen.locus of control: intern.vs. ext. – pre	18.41 (16.80)	26.24 (19.18)	20.74 (14.77)	$F(2,56) = 1.07$, $p = .35$, $eta^2 = .04$
Gen. locus of control: intern.vs. ext. – pre	16.23 (15.25)	29.19 (20.38)	19.53 (12.31)	$F(2,56) = 3.23$, $p = .04$, $eta^2 = .11$
Sense of coherence				
SOCL-9 - pre	44.00 (9.10)	49.81 (8.56)	46.47 (6.54)	$F(2,56) = 2.46$, $p = .09$, $eta^2 = .08$
SOCL-9 – post	43.53 (7.90)	52.29 (8.01)	47.05 (6.66)	$F(2,56) = 6.50$, $p = .00$, $eta^2 = .19$
Perceived self-efficacy				
SWE - pre	29.82 (4.00)	31.57 (4.76)	29.63 (3.37)	$F(2,56) = 1.35$, $p = .27$, $eta^2 = .05$
SWE – post	30.47 (3.39)	32.67 (4.22)	30.21 (2.57)	$F(2,56) = 2.98$, $p = .06$, $eta^2 = .10$

Table 13. Pre/post comparison of the groups for depression, anxiety, perceived stress and stress reactivity

Questionnaires	Kine Group (n = 17)	SIT Group (n = 21)	Control Group (n = 19)	Statistics
Depression				
ADS-K – pre	27.82 (5.72)	22.81 (5.84)	26.68 (6.42)	$F(2,56) = 3.74$, $p = .03$, $eta^2 = .12$
ADS-K – post	26.88 (6.91)	20.81 (4.60)	23.42 (6.97)	$F(2,56) = 4.53$, $p = .01$, $eta^2 = .14$
Anxiety				
STAI-t - pre	48.12 (1.87)	48.09 (3.16)	48.89 (2.90)	$F(2,56) = .52$, $p = .59$, $eta^2 = .02$
STAI-t - post	48.88 (3.46)	48.28 (1.85)	48.00 (2.69)	$F(2,56) = .49$, $p = .61$, $eta^2 = .02$
Perceived Stress Scale				
PSS – pre	27.88 (5.79)	23.67 (5.94)	25.47 (6.83)	$F(2,56) = 2.17$, $p = .12$, $eta^2 = .07$
PSS – post	26.29 (5.97)	20.38 (4.96)	23.89 (7.11)	$F(2,56) = 4.62$, $p = .01$, $eta^2 = .15$
Stress Reactivity Scale				
Work overload – pre	9.94 (2.92)	9.14 (2.39)	9.47 (2.09)	$F(2,56) = .49$, $p = .61$, $eta^2 = .02$
Work overload – post	9.65 (2.47)	8.24 (2.47)	9.16 (2.36)	$F(2,56) = 1.66$, $p = .19$, $eta^2 = .06$
Social conflicts – pre	13.82 (2.38)	13.62 (2.73)	12.95 (2.44)	$F(2,56) = .61$, $p = .55$, $eta^2 = .02$
Social conflicts – post	13.82 (2.21)	12.28 (3.12)	12.84 (2.43)	$F(2,56) = 1.60$, $p = .21$, $eta^2 = .06$
Social appraisal – pre	11.29 (2.99)	9.76 (2.77)	9.95 (2.20)	$F(2,56) = .18$, $p = .06$, $eta^2 = .06$
Social appraisal – post	10.47 (2.35)	9.14 (2.92)	9.79 (2.10)	$F(2,56) = 1.33$, $p = .27$, $eta^2 = .05$
Failure at work – pre	11.29 (2.05)	11.14 (1.80)	10.74 (2.40)	$F(2,56) = .35$, $p = .71$, $eta^2 = .01$
Failure at work – post	10.88 (2.34)	10.00 (1.73)	10.74 (1.63)	$F(2,56) = .1.21$, $p = .30$, $eta^2 = .04$
Pre-Stress-Phase – pre	9.76 (1.79)	8.19 (2.23)	8.53 (1.84)	$F(2,56) = 3.19$, $p = .05$, $eta^2 = .11$
Pre-Stress-Phase – post	9.06 (1.75)	7.43 (2.29)	9.00 (1.76)	$F(2,56) = 4.36$, $p = .02$, $eta^2 = .14$
Post-Stress-Phase – pre	8.29 (2.02)	8.67 (2.10)	8.95 (1.51)	$F(2,56) = .53$, $p = .59$, $eta^2 = .02$
Post-Stress-Phase – post	8.23 (1.92)	9.33 (1.65)	9.00 (1.63)	$F(2,56) = 1.94$, $p = .15$, $eta^2 = .07$
Total stress reactivity - pre	64.41 (8.33)	60.52 (7.85)	60.58 (7.66)	$F(2,56) = 1.41$, $p = .25$, $eta^2 = .05$
Total stress reactivity - post	62.12 (8.16)	56.43 (9.48)	60.53 (7.68)	$F(2,56) = 2.30$, $p = .11$, $eta^2 = .08$

However, when the groups were observed separately a different picture emerged. While the KIG and the CG did not increase in well-being over time the SMG developed positively in several psychometric characteristics (Table 14).

Table 14. Trainingeffects of the stress management group (SMG) over the examination period

Questionnaires	*SMG (n = 21)*		*Statistics*
	pre	*post*	
Selfconcept of own competence (FKK)	*35.09 (6.41)*	*36.52 (6.01)*	*F(1,20) = 4.178, p = .054, eta² =.173*
Depression Scale (ADS-K)	*7.81 (5.84)*	*5.81 (4.60)*	*F(1,20) = 5.455, p = .030, eta² =.214*
Perceived Stress Scale (PSS)	*23.67 (5.94)*	*20.38 (4.96)*	*F(1,20) = 19.520, p = .000, eta² =.494*
Stress Reactivity Scale overall (SRS)	*60.52 (7.85)*	*56.43 (9.48)*	*F(1,20) = 20.851, p = .000, eta² =.510*
Sense of Coherence (SOCL-9)	*49.81 (8.56)*	*52.29 (8.01)*	*F(1,20) = 15.972, p = .001, eta² =.444*
Perceived Self-Efficacy (SWE)	*31.57 (4.76)*	*32.67 (4.22)*	*F(1,20) = 4.350, p = .050, eta² =.179*

Over the observation period depressive affect and negative thought patterns assessed by the ADS-K diminished 25.6% (p=.030) as well as perceived stress, measured by the PSS, which decreased 13.9% (p=.000) and the SRS, which assessed the experience of typical stress reactivity and changed 6.75% (p=.000) compared to pre-training. Furthermore, the sense of coherence, the dynamic feeling of optimism and control regarding the future, measured with the SOC increased 4.9% (p=.001) as well as perceived self-efficacy measured with SWE was found to be 3.7% elevated (p=.050) and the self concept of own ability showed a positive trend (p=.054) over time.

7 Discussion

The primary purpose of this effectiveness study was to evaluate the effects of kinesiology and cognitive behavioral stress management on psychological well-being to an acute stressor in healthy women and men. Therefore, we performed a randomized controlled effectiveness intervention study. A secondary goal was to review and promote a test procedure, which could be utilized for intervention studies in different methods of complementary medicine.

At first sight the primary and secondary outcome measures did not reveal notable information other that the three groups did not differ in them. However, as we immersed into the data we found that the relevance of the study lies in a methodological hindsight. However, we see three key findings: 1) The study design has proved to be efficient and the participants in all three groups reacted to the TSST and it evoked comparable patterns in saliva cortisol. Although the participants in the three groups showed a stress response to the TSST we were unable to find relevant group differences. 2) At the outset of the study we allocated the participants by chance to prevent biases that could affect the course of the study. Although we performed adequate randomization the KIG exhibited meaningfully higher depression scores than both other groups. Furthermore, the evidence suggests that additional psychological characteristics that may influence coping with stress have not been evenly distributed already at baseline. 3) While the kinesiology and the control group did not differ in the course of the observation period, we found that in the psychometric components relevant for psychological health, the stress management group developed extraordinarily positive. However, this effect is observed only if the group is looked at separately.

The first finding concerned the study design. Various psychological methods, but also such from complementary medicine claim to reduce psycho-social stress and promote well-being. Our study design has proved to be resource-efficient, reproducible and reliable to test such hypotheses. As in the predecessor studies (Gaab et al., 2003; Hammerfald et al., 2006; Storch et al., 2007) we were able to induce stress and measure the reactivity pattern in all groups. But

as the groups already differed substantially at outset of the study it cannot be ruled out that this might have confounded the results, thus comparing the treatment groups might be interpreted as futile. For the sake of completeness, it should be noted that we also see the skewness of distribution of psychometric variables and the participants variance in relation to the sample size which might have been too large compared to the effects as further explanation for not finding group differences in the TSST. For the SMG we found a dissociation between emotional development over the evaluation period and the response during the TSST. When observed separately we found the participants of the stress management group developed favorably in all psychometric components but during the stress test the group performed similarly compared to the other two groups. According to Campbell and Ehlert (2012) this dissociation between cortisol responses and perceived emotional stress variables have been found in approximately 75% of the studies with TSST. Therefore, the positive development during the experimental phase is not in conflict with the current literature but rather reflects a normal reactivity pattern and/or results from various methodological issues (Campbell & Ehlert, 2012). Due to the fore mentioned differences at outset of the study it is difficult to derive reliable assertions for the KIG from the results observed. It is conceivable that the training was too short to have substantial effect. Our treatment lasted two consecutive days while Gaab et al. (2003) taught for two days with interval and active training time in between training-dates, while Storch et al. (2007) trained on two consecutive weekends (each 3 days) as well as a booster session. This resulting in over three times as much training time. But it is also cogitable that the kinesiology treatment compiled for healthy individuals did not focus enough on the relevant characteristics of the group treated and a treatment that would have focused more on the depressive affect would have been better suited. And lastly it cannot be ruled out that the training as such was not effective towards developing resilience.

As to the second key finding, the Swiss Federal Council (2013) urged in its “Health 2020” strategy to promote health by means of prevention to raise health competence and improve well-being in the healthy general public. It was therefore perspicuous that we utilized a pragmatic trial, a term coined by Schwartz and Lellouch (1967), to evaluate the two interventions as well as the control group. This trial form, also referred to as effectiveness study, ensures closeness to real-world practice (Singal et al., 2014), delivers higher external validity

and relevance for providers in practice and policy-makers to decide confidently. Irrespective of the trial form to utilize statistical theory random sampling is imperative. Only this can ensure that the compared groups do not differ in any systematic way at the outset (Altman & Bland, 1999). For this reason as well as the fact that we strictly followed the study design of our precursors (Gaab et al., 2003; Hammerfald et al., 2006; Storch et al., 2007) we chose the following allocation process: we blindly randomized each participant and to the best of our knowledge to one of the groups. As described earlier this procedure led to groups that differed meaningfully regarding the extent of depressive symptomatology. At pre-measurement the median depression score of the KIG was one standard deviation higher than the median of the SMG. In terms of helpful characteristics towards stress management the kinesiology group exhibited baseline scores that were in 89.5% the least preferable of all three groups. Conversely, the SMG demonstrated already at baseline in all psychometric characteristic associated with favorable stress-coping the most preferable scores. This may be interpreted as supposition that the groups differed in their resources of managing stress already at the outset of the study. Our study used almost identical exclusion criteria, but while Gaab et al. (2003) and Storch et al. (2007) recruited young male students only and Hammerfald et al. (2006) recruited both gender but second year psychology students only, our study recruited also healthy participants but more representative of the general population with the age group being between 20 and 50 years old. We assume that in narrow, homogenous populations the variation is smaller and that this difference might have been the root cause that led to the different groups. Random assignment makes groups comparable only when the sample is large. Saint-Mont and Tu (2015) even argue that in small to medium sized samples random allocation of subjects to treatments yield considerable imbalance between the groups and that confounding due to randomization is more the rule rather than the exception. Extended procedures have been suggested to keep the groups balanced for certain prognostic patient characteristics. These may be stratified randomization or minimization where group allocation does not rely solely on chance but is designed to reduce any difference in the distribution of known or suspected determinants of outcome, so that any effect can be attributed to the treatment under test (Altman & Bland, 1999). At the beginning of the trial it is determined which factors need to be represented equally in the groups. Then group allocation is made, but not purely by chance, but by determining in which group inclusion the person would mini-

mize any differences in these predefined factors (Treasure & MacRae, 1998). Thus, if group A has higher depression scores as well as higher age, but other variables being equal, the next elderly with higher depression scores is likely to be allocated to group B. The allocation process may then still involve chance with a blinded individual but "with the dice loaded" in favor of the allocation which minimizes the differences (Treasure & MacRae, 1998). We propose for future pragmatic studies in the norm population to at least stratify or minimize for the most prevalent disorders such as depression, anxiety and stress. This could help ensure, rather than hope for, that groups are going to be comparable.

Thirdly and finally, we report the training effects of the stress-management group over the course of the observation period. In the post measurement we found that all psychometric components relevant for psychological health had developed in the preferable direction. In the following characteristics the development over the observation period was especially evident: a) we found the group less depressive, with less negative thoughts as well as less stressed and b) the participants exhibited a stronger self-concept, higher self-efficacy as well as an improved sense of coherence. In summary, the stress management group became more resilient. As the groups were comparable in all but the psychometric characteristics, where the depression scores protrude, we hypothesize that this difference as well as the training might have led to the positive development of the group. The evidence also converges as the encumbering psychometric variables diminished while parallel the health supporting ones flourished. This leads us to the supposition that the responsiveness to a prevention program might be influenced by psychological condition as well as the coping resources of the individual at outset of the training program. We conceive this as a potential psychological "trampoline effect". Therefore, the stress coping resources at the start of the program could be seen as moderator that affects the strength of the relationship between the content of the program and the responsiveness to it. To follow the above mentioned analogy, the weight of the object could be seen as the content of the program which is equal for every participant, but the resilience-effect accruing originates from the interaction of the individuals' resources with it. This could imply that more developed coping skills at outset of the training could be acting as "springs with more energy stored" and therefore enabling in depth change, while participants with elevated depression scores might have "more rigid springs" and therefore might be

less able to profit from the stress management program. It could be hypothesized that the latter could profit at first more from a different training program specifically addressing the depressive symptomatology to become more receptive for the following stress management training. This program could focus on symptoms associated with depression such as loss of interest, decreased energy, low mood, poor concentration or pessimism. Subsequent the stress management program could be taught and be more effective.

However, there are limitations to our study. Firstly, the number of participants was relatively small and due to nature of an effectiveness study the variance found was large. It is therefore possible that the sample size was too small in order to find the expected differences. Secondly, due to the higher depression scores of the kinesiology group we cannot derive reliable assertions regarding the effectiveness for stress management of the kinesiology training. It might be assumed that the overall psychometric scores of the more depressed participants considerably inhibited hypothesized changes over time.

Finally, based on this study we strongly suggest that in future effectiveness studies more elaborated allocation methods are used in order to balance the potential key influence factors. While elaborated randomization has been a complex task in the past, the use of software programs will make enhanced randomization processes much easier to implement. This will make the use of resources in research more effectively. Furthermore, we suggest to utilize the proposed research protocol for evaluation of complementary medicine methods that claim that their method is useful to strengthening resources against acute stress. And last but not least, we encourage future studies to elaborate in more detail the evidence that the effect of stress management training with people that are resourceful already at the beginning of the training can lead to outstanding positive development of resilience. A potential psychological trampoline effect would have important implications for the use of stress management and other psychological health trainings in the future.

Conflict of interest

The author declares that there have been no conlicts of interest.

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9 Appendix

9.1 Probandeninformation und Einverständniserklärung

Zürich, 19. Dezember 2010

Information für Probandinnen und Probanden

Die Wirksamkeit von Integrativer Kinesiologie und Stressmanagement Training als Stresspräventionsmassnahme. Eine randomisierte, Warteliste-kontrollierte Studie mit gesunden ProbandInnen.

Sehr geehrte Probandin,
Sehr geehrter Proband,

Sie haben sich dafür interessiert an der oben erwähnten Studie teilzunehmen und erfüllen die Kriterien zur Studienteilnahme. Das freut uns. Unsere Studie zur Untersuchung der Wirksamkeit von zwei Stresspräventionsmassnahmen bei gesunden Personen wird am Psychologischen Institut – Klinische Psychologie und Psychotherapie, Zürich durchgeführt.

In diesem Schreiben informieren wir Sie detailliert und offen über sämtliche Schritte der Untersuchung damit Sie sich entscheiden können, ob Sie an unserer Studie teilnehmen möchten oder nicht. Selbstverständlich können Sie uns jederzeit auch telefonisch erreichen und uns zur Studie weitere Fragen stellen (Tel. 079 642 45 15, Lars Sonderegger – Studienleiter).

Studienziel

Diese Studie soll Aufschluss darüber geben, inwiefern und ob Integrative Kinesiologie und ein Stressmanagement-Training als Stresspräventionsmassnahme wirksam sind. Beide Methoden sind in der Schweiz bewährt und weit verbreitet. Nun soll untersucht werden ob sich ein Nutzen wissenschaftlich erfassen und dokumentieren lässt.

Hintergründe und allgemeine Informationen

Stress ist ein Schlagwort welches eine positive und negative Bedeutung hat. Stress ist dann negativ, wenn er als unangenehm erlebt wird und eine Distanzierung „zum Stressor“ zunehmend schwierig ist. Eine gute funktionierende Stressbewältigung ist entscheidend um die Lebensqualität zu erhalten. In der Schweiz beurteilten 41% der Erwerbstätigen ihren Beruf als psychisch und nervlich belastend. In unserer Studie geht es darum zwei Methoden die möglicherweise wirksam gegen Stress sind zu evaluieren.

Heute werden Stressmanagement-Techniken aus der Psychologie aber auch aus der Komplementärmedizin oft angewandt. Das eine Training, genannt, Stressimpfungstraining (SIT) nach Meichenbaum, hat sich als kognitiv-verhaltenstherapeutische Intervention in mehreren Studien als wirksam erwiesen. Beim anderen Training handelt es sich um eine der am häufigsten durch die Zusatzversicherungen der Krankenkassen vergüteten Methoden, die Integrative Kinesiologie (IK). Die IK entwickelte sich aus der person-zentrierten Gesprächsansatz nach Rogers und verbindet Gesprächstherapie mit einfachen Körperaktivierungstechniken. In beiden Methoden lernen die Teilnehmenden den Umgang mit ihren Emotionen und Kognitionen verstehen und potenziell zu verändern.

Mit der Studie soll abgeklärt werden, ob und wie stark sich die Methoden stresspräventiv im Alltag auswirken und welchen Einfluss sie auf die Stressbewältigung in einer Leistungssituation haben. Es werden 64 ProbandInnen in die Studie aufgenommen. Jede Person wird nach dem Zufallsprinzip entweder einer Trainingsgruppe oder der Wartelisten-Kontrollgruppe zugeteilt.

Diese Studie wird nach geltenden schweizerischen Gesetzen und nach international anerkannten Grundsätzen durchgeführt.

Freiwilligkeit der Teilnahme und Ausstieg

Ihre Teilnahme an dieser Studie ist freiwillig und ohne finanzielle Vergütung. Sie erhalten kostenlos eine psychologisches oder ein integrativ-kinesiologisches Training. Da neben den beiden Ausbildungsgruppen eine Wartelisten-Kontrollgruppe geführt wird, können die Teilnehmenden dieser Gruppe im Anschluss an das Studienende das Training ebenfalls kostenlos und unverbindlich absolvieren.

Die Einwilligung zur Teilnahme an dieser Studie können Sie ohne Angaben von Gründen jederzeit zurückziehen. Im Falle eines Widerrufes werden die bis zu diesem Zeitpunkt erhobenen Daten weiter verwendet. Sollte während der Studie oder beim Studienabbruch das Wohlbefinden durch die Studie unerwarteterweise beeinträchtigt werden, können Sie sich kostenlos beim Institut für Klinische Psychologie und Psychotherapie untersuchen lassen.

Studienablauf

1. Aufnahmegespräch und Prä-Messung

Sind Sie nach dem Lesen dieser Information noch immer an der Studienteilnahme interessiert, nehmen Sie bitte mit dem Studienverantwortlichen Herrn Lars Sonderegger Kontakt auf, damit ein Termin für ein Aufnahmegespräch vereinbart werden kann. Bei diesem werden Sie nochmals mündlich über die wesentlichen Punkte der Studie informiert und allfällige noch offene Fragen werden geklärt. Aus juristischen Gründen ist vor Aufnahme in die Studie eine Einverständniserklärung zu unterschreiben. Im Anschluss füllen Sie die erste Fragebogenmessung (Prä-Messung) zur Erfassung der Ausgangswerte vor Beginn der Studie aus. Der Zeitaufwand für diese Sitzung beträgt ca. 40 Minuten.

2. Training in der IK Kinesiologie oder Stressmanagement-Gruppe

Die Trainings werden jeweils mit einer Trainerin / einem Trainer einmal wöchentlich stattfinden und jeweils 60 Minuten dauern und wird 7 Einheiten, also 7 Wochen dauern. Alle Trainings werden an zentraler Lage in Zürich oder in Oerlikon an der Universität Zürich stattfinden. Eine genaue Anfahrtsbeschreibung mit Plan erhalten Sie via Email zwei Wochen vor dem ersten Training.

3. Messung

Unmittelbar nach Trainingsende werden Sie gebeten eine Fragebogenserie online, auf Wunsch auch auf Papier möglich, auszufüllen. Der Zeitaufwand hierfür beträgt ca. 30 – 40 Minuten. Damit werden wir die ersten Effekte der Trainings messen.

4. Leistungsmessung am Psychologischen Institut

Für alle Teilnehmenden findet nach Abschluss der Trainings eine Leistungsmessung statt. Bei dieser Untersuchung werden acht Speichelproben mittels Salivetten (Wattebäuschchen) gesammelt und auf ein Stress-Hormon (Cortisol) und ein Speichelenzym (Alpha-Amylase) ausgewertet. Dies ist vergleichbar mit dem Kauen eines Wattebausches. Die psychischen Parameter werden anschliessend mittels Fragebögen untersucht. Der Zeitaufwand hierfür beträgt ca. 2 Stunden.

5. Follow-up Messung

Bei dieser werden alle Studienteilnehmenden gebeten 2 Wochen nach dem Leistungstest eine abschliessende Fragebogenserie online, auf Wunsch auch auf Papier möglich, auszufüllen. Der Zeitaufwand hierfür beträgt ca. 30 – 40 Minuten. Mit dem Ausfüllen der Follow-up Fragebögen wird die Studie regulär beendet. Anschliessend können die Teilnehmenden aus der Wartlisten-Kontrollgruppe das Training ebenfalls besuchen.

Pflichten der ProbandInnen und des Prüfers

Als StudienteilnehmerIn verpflichten Sie sich, den Studienplan wie hier beschrieben einzuhalten und den Prüfungsleiter über allfällige unerwünschte Wirkungen zu informieren. Ebenfalls würden Sie den Prüfungsleiter während des Zeitraums des Experimentes über Behandlungen bei einem Arzt und über die Einnahme von Arzneimitteln zu informieren. Zu den Arzneimitteln gehören auch alle selbstgekauften, ohne ärztliches Rezept erhältlichen und/oder alternativmedizinischen Präparate (Kräuter, Pflanzen, homöopathische und spagyrische Essenzen, asiatische Heilmittel und Vitamine).

Ihr Nutzen durch die Teilnahme

Sie haben die Gelegenheit ein Training von sieben Einheiten zu Stressmanagement kostenlos zu besuchen. In der Privatwirtschaft angebotene vergleichbare Trainings kosten knapp 1000 CHF. Möglicherweise kann dies zu einem verbesserten Umgang mit Stresssituationen im Alltag führen. Eine weitergehende finanzielle Entschädigung wird nicht geleistet.

Risiken welche durch die Teilnahme entstehen könnten

Beide Trainingsmethoden sind unbedenklich und es sind keinerlei Nebenwirkungen bekannt. Insbesondere werden während der gesamten Studie keinerlei Medikamente verabreicht noch invasive Messungen durchgeführt.

Für gebärfähige Frauen

Aus Vorsichtsgründen ist Schwangerschaft ein Ausschlusskriterium für die Studienteilnahme. Sollte hierüber Unklarheit bestehen, kann jederzeit kostenlos ein Schwangerschaftstest durchgeführt werden. Studienteilnehmerinnen werden gebeten während der Trainings eine zuverlässige nicht-hormonelle Methode der Verhütung anzuwenden (doppelte mechanische Verhütungsmethode, wie z.B. Diaphragma, Spirale usw. in Kombination mit Präservativ). Probandinnen, die während des Trainings schwanger werden, müssen den Prüfungsexperten umgehend informieren. In diesem Fall werden die Probandinnen vorsichtshalber von der weiteren Studienteilnahme ausgeschlossen. Frauen in der Stillzeit sind ebenfalls von der Studienteilnahme ausgeschlossen.

Vertraulichkeit der Daten

In dieser Studie werden Daten von Ihnen erfasst. Während der ganzen Studie und bei den erwähnten Kontrollen wird die Vertraulichkeit strikt gewahrt. Ihr Name wird in keiner Weise in Rapporten oder Publikationen, die aus der Studie hervorgehen, veröffentlicht. Diese werden anonymisiert und sind ausschliesslich Fachleuten zur wissenschaftlichen Auswertung zugänglich. Die zuständige Ethikkommission kann im Rahmen eines sog. Monitorings oder Audits die Durchführung der Studie überprüfen und dabei Einsicht in Ihre Originaldaten nehmen.

Kosten

Die in dieser PatientInneninformation erwähnten Untersuchungen, Auswertungen und Trainings sind kostenlos. Weder Ihnen noch Ihrer Krankenkasse entstehen im Zusammenhang mit Ihrer Teilnahme Kosten.

Unfreiwilliger Studienabbruch

Ihre Teilnahme kann durch den Prüfungsleiter bei gewichtigen Gründen abgebrochen werden. Falls die Studie aus irgendeinem Grund abgebrochen wird, werden Sie über die Gründe informiert. In diesem Fall ist zu Ihrer Sicherheit eine Abschlussbesprechung notwendig.

Kontaktpersonen

Bei Unklarheiten, Notfällen, unerwarteten oder unerwünschten Ereignissen, die während der Studie oder nach deren Abschluss auftreten, können Sie sich jederzeit an die untenstehenden Kontaktpersonen wenden:

Herr lic. phil. Lars B. Sonderegger (Prüfer)
Psychologisches Institut – Klinische Psychologie und Psychotherapie
Universität Zürich
Binzmühlestrasse 14 / Box 26
CH – 8050 Zürich
Notfallnummer mit 24h Erreichbarkeit : 079 642 45 15

Schriftliche Einverständniserklärung

Bitte lesen Sie dieses Formular sorgfältig durch und fragen Sie, wenn Sie etwas nicht verstehen oder wissen möchten.

Titel der Studie

Psychoneuroendokrinologische Wirksamkeitsstudie zu einer kognitiv-verhaltensthera-peutischen und einer integrativ-kinesiologischen Intervention bei gesunden Erwachsenen.

Ort der Studie

Universität Zürich

Prüfer

Lars B. Sonderegger, lic. Phil.
Email: lars.sonderegger@ikamed.ch
Sennhofweg 20, 8125 Zollikerberg, Tel. 079 642 45 15

Probandin/Proband ☐ männlich ☐ weiblich

Name _____

Vorname _____

Geburtsdatum: _____

- Ich wurde vom unterzeichnenden Prüfer mündlich und schriftlich über die Ziele, den Ablauf der Studie, über die zu erwartenden Wirkungen, über mögliche Vor- und Nachteile sowie über eventuelle Risiken informiert.

- Ich habe die zur oben genannten Studie abgegebene schriftliche Probandeninformation gelesen und verstanden. Meine Fragen im Zusammenhang mit der Teilnahme an dieser Studie sind mir zufriedenstellend beantwortet worden. Ich kann die schriftliche Probandeninformation behalten und erhalte eine Kopie meiner schriftlichen Einverständniserklärung.

- Ich hatte genügend Zeit, um meine Entscheidung zu treffen.

- Ich weiss, dass meine persönlichen Daten nur in anonymisierter Form an aussenstehende Institutionen zu Forschungszwecken weitergegeben werden. Ich bin einverstanden, dass die zuständigen Fachleute der Kantonalen Ethikkommission zu Prüf- und Kontrollzwecken in meine Originaldaten Einsicht nehmen dürfen, jedoch unter strikter Einhaltung der Vertraulichkeit.

- Ich nehme an dieser Studie freiwillig teil. Ich kann jederzeit und ohne Angabe von Gründen meine Zustimmung zur Teilnahme widerrufen. In diesem Fall werde ich zu meiner Sicherheit abschliessend psychologisch-medizinisch untersucht.

- Ich bin mir bewusst, dass während der Studie die in der Probandeninformation genannten Anforderungen und Einschränkungen einzuhalten sind.

- Im Interesse meiner Gesundheit kann mich der Prüfer jederzeit von der Studie ausschliessen. Zudem orientiere ich den Prüfer über die Behandlung bei einem anderen Arzt sowie über die Einnahme von Medikamenten (vom Arzt verordnete oder selbständig gekaufte).

Ort, Datum	Unterschrift der Probandin/des Probanden

Bestätigung des Prüfers: Hiermit bestätige ich, dass ich dieser ProbandIn Wesen, Bedeutung und Tragweite der Studie erläutert habe. Ich versichere, alle im Zusammenhang mit dieser Studie stehenden Verpflichtungen zu erfüllen. Sollte ich zu irgendeinem Zeitpunkt während der Durchführung der Studie von Aspekten erfahren, welche die Bereitschaft der ProbandIn zur Teilnahme an der Studie beeinflussen könnten, werde ich sie resp. ihn umgehend darüber informieren.

Ort, Datum	Unterschrift des Prüfers / Lars B. Sonderegger

9.2 Genehmigungsschreiben der Ethikkommission

Kantonale Ethik-Kommission Zürich (KEK)

Kantonale Ethikkommission (KEK)
Präsident
Prof. Dr. Robert Maurer
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Herr
lic. phil. Lars B. Sonderegger
Sennhofweg 20
8125 Zollikerberg

Zürich,19. Januar 2011

Formular für die
Beschlussmitteilung der Ethikkommission Zürich

Die Kantonale Ethikkommission des Kanton Zürich hat das folgende Forschungsprojekt per Präsidialentscheid begutachtet.

Titel des Forschungsprojektes Studiencode: Ref. Nr. EK: KEK-ZH-NR: 2011-0004/0

Psychoneuroendokrinologische Wirksamkeitsstudie zu einer kognitiv-verhaltenstherapeutischen und einer integrativ-kinesiologischen Intervention bei gesunden Erwachsenen

Zusammensetzung der Ethikkommission

Die Ethikkommission tagte in der nachfolgend erwähnten Zusammensetzung und war damit beschlussfähig (Art. 32 und Art. 10 Abs. 3 der Verordnung über klinische Versuche mit Heilmitteln vom 17.10.2001 in Verbindung mit § 9 des Reglements der Kantonalen Ethikkommission).

					am Beschluss beteiligt		
					ja	nein	
	Name, Vorname	Berufliche Stellung / Titel	m	f		abwesend	in Ausstand
Vorsitz	Maurer Robert	Prof. Dr. med.	☒	☐	☒	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
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			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐
			☐	☐	☐	☐	☐

Die Ethikkommission kommt zu folgendem **Beschluss**:

- ☐ **A positiv**
- ☐ **B mit Empfehlungen**
- ☐ **C Auflagen**
  - ☐ Nachbegutachtung durch Ethikkommission notwendig
  - ☐ Schriftliche Mitteilung an Ethikkommission ausreichend
- ☐ **D negativ (mit Begründung und Erläuterung für die Neubeurteilung)**
- ☒ **E Nicht-Eintreten (mit Begründung)**

Der Beschluss gilt auch für die namentlich aufgeführten weiteren PrüferInnen im Zuständigkeitsbereich der Ethikkommission (gemäss separater detaillierter Liste)

Hauptprüfer/in (verantwortliche/r Studienleiter/in am Versuchsstandort)

Name, Vorname, Titel: Sonderegger Lars B., lic. phil.

Funktion: Studienleiter

Adresse: Sennhofweg 20, 8125 Zollikerberg

Die Ethikkommission stützt ihre Beurteilung auf die Unterlagen, wie sie aufgeführt sind:

- ☒ im „Basisformular zur Einreichung eines biomedizinischen Forschungsprojektes" 19.12.2010
- ☒ im Begleitbrief des Gesuchstellers an die KEK vom 22.12.2010
- ☐ in der Rubrik „begutachtete Unterlagen" (siehe weiter unten)
- ☐

Art des Verfahrens:

- ☐ normales Verfahren
- ☒ vereinfachtes Verfahren
- ☐ Nachbegutachtung

Die Ethikkommission kommt zu folgendem **Beschluss**:

- ☐ **A positiv**
- ☐ **B mit Empfehlungen**
- ☐ **C Auflagen**
  - ☐ Nachbegutachtung durch Ethikkommission notwendig
  - ☐ Schriftliche Mitteilung an Ethikkommission ausreichend
- ☐ **D negativ (mit Begründung und Erläuterung für die Neubeurteilung)**
- ☒ **E Nicht-Eintreten (mit Begründung)**

Der Beschluss gilt auch für die namentlich aufgeführten weiteren PrüferInnen im Zuständigkeitsbereich der Ethikkommission (gemäss separater detaillierter Liste)

Begründung für Nicht-Eintreten
Eine Prüfung der Gesuchsunterlagen hat ergeben, dass es sich beim Forschungsprojekt weder um eine Heilmittelstudie handelt noch um eine Studie, die gemäss § 1 des Patientengesetzes in den Zuständigkeitsbereich der Kantonalen Ethikkommission fällt. Infolge dessen bedarf es für die Durchführung dieser Studie keiner Bewilligung der Kantonalen Ethikkommission.

(erweiterbar)

2011-0004/0 4 / 4

Pro Memoria: **Pflichten des/der Hauptprüfers/in**

- Meldepflicht bei:
  - a) schwerwiegenden unerwünschten Ereignissen unverzüglich (Arzneimittel: nur bei schwerwiegenden unerwarteten Nebenwirkungen)
  - b) neuen Erkenntnissen, die während des Versuchs verfügbar werden und die Sicherheit der Versuchspersonen und/oder die Weiterführung des Versuchs beeinflussen können.
  - c) Änderung des Protokolls (Versuchsplans)
  - d) Ende oder Abbruch der Studie
- Zwischenbericht: einmal pro Jahr
- Meldungs- oder Bewilligungspflicht von Studien bei Swissmedic bzw. anderen Bundes- oder kantonalen Behörden (bei gesponserten Studien ist dies die Pflicht des Sponsors)
- Schlussbericht

Die Ethikkommission bestätigt, dass sie nach ICH-GCP arbeitet.

Rechtsmittelbelehrung:

Gegen diesen Beschluss kann innert dreißig Tagen, von der Mitteilung an gerechnet, beim Regierungsrat des Kantons Zürich schriftlich Beschwerde eingereicht werden. Die Beschwerdeschrift muss einen Antrag und dessen Begründung enthalten. Der angefochtene Entscheid ist beizulegen oder genau zu bezeichnen. Die angerufenen Beweismittel sind genau zu bezeichnen und soweit möglich beizulegen.

Für die Ethikkommission:

Ort, Datum: Zürich, 19. Januar 2011

9.3 Statement of authorship

I hereby declare that I am the sole author of this dissertation and that I have not used any sources other than those listed in the bibliography and identified as references. I further declare that I have not submitted this thesis at any other institution in order to obtain a degree.

Zollikerber, .../...../2017 _____

Lars B. Sonderegger

9.4 Curriculum Vitae Lars B. Sonderegger

Personalien

Vorname Lars B.
Nachname Sonderegger
Adresse Sennhofweg 20; CH – 8125 Zollikerberg
Geburtsdatum 20. Juli 1972

Akademischer Werdegang

2011 – heute Dissertation an der Universität Zürich, Dr. cand.
2011 - heute Weiterbildung im Bereich Beratung und Coaching
1996 – 2002 Lizentiatsstudium an der Universität Zürich, M. Sc.
Fachrichtung: Psychologie, Psychopathologie und Neurophysiologie
1988 – 1991 Eidg. Dipl. Kaufmann (Berufsausbildung mit Berufsmaturität)

Beruflicher Werdegang

2017 – heute Dozent an der HSLU Hochschule Luzern
2016 – heute Verwaltungsrat, K. Müller AG
2006 – heute Gründer und CEO Quantonomics LLC
2015 – heute Verwaltungsratspräsident IKAMED Institute AG
2005 – 2015 Eigentümer und Geschäftsleitung
IKAMED Institute AG

Mandate und Netzwerke

2016 – heute Founding Member World Innovations Forum (WIForum)
2014 – heute Member Global Thinktank World Tourism Forum Lucerne (WTFL)
2005 – 2014 Stiftungsratsmitglied
Stiftung für die Erhaltung, Förderung und Weiterentwicklung des Person-zentrierten Ansatzes